No. 17-1229	
Title:	Helsinn Healthcare S.A., Petitioner v. Teva Pharmaceuticals USA, Inc., et al.
Docketed:	March 2, 2018
Lower Ct:	United States Court of Appeals for the Federal Circuit
Case Numbers:	(2016-1284, 2016-1787)
Decision Date:	May 1, 2017
Rehearing Denied:	January 16, 2018
Questions Presented	

DATE	PROCEEDINGS AND ORDERS
Feb 28 2018	Petition for a writ of certiorari filed. (Response due April 2, 2018) **Petition** **Appendix** **Certificate of Word Count** **Proof of Service**
Mar 12 2018	Motion to extend the time to file a response from April 2, 2018 to May 17, 2018, submitted to The Clerk. **Main Document**
Mar 13 2018	Motion to extend the time to file a response is granted in part and the time is extended to and including May 11, 2018.
Mar 13 2018	Blanket Consent filed by Petitioner, Helsinn Healthcare S.A.. **Blanket Consent**
Mar 19 2018	Blanket Consent filed by Respondents, Teva Pharmaceuticals USA, Inc., et al.. **Blanket Consent**
Mar 27 2018	Brief amicus curiae of Congressman Lamar Smith filed. **Main Document** **Proof of Service** **Certificate of Word Count**
Mar 30 2018	Brief amicus curiae of American Intellectual Property Law Association filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Mar 30 2018	Brief amicus curiae of Intellectual Property Owners Association filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Apr 02 2018	Brief amicus curiae of Pharmaceutical Research and Manufacturers of America

	filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Apr 02 2018	Brief amicus curiae of Bar Association of the District of Columbia filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Apr 02 2018	Brief amicus curiae of The Naples Roundtable filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Apr 02 2018	Brief amicus curiae of Boston Patent Law Association in support of neither party filed. **Main Document** **Proof of Service** **Certificate of Word Count**
Apr 02 2018	Brief amicus curiae of The Massachusetts Biotechnology Council filed. **Proof of Service** **Certificate of Word Count** **Main Document**
Apr 02 2018	Brief amicus curiae of The Biotechnology Innovation Organization (BIO) filed. **Main Document** **Certificate of Word Count** **Certificate of Word Count**
Apr 02 2018	Brief amicus curiae of US Inventor, Inc. filed. **Main Document** **Certificate of Word Count** **Proof of Service**
May 11 2018	Brief of respondents Teva Pharmaceuticals USA, Inc., et al. in opposition filed. **Main Document** **Other** **Proof of Service** **Certificate of Word Count**
May 29 2018	DISTRIBUTED for Conference of 6/14/2018.
May 29 2018	Reply of petitioner Helsinn Healthcare S.A. filed. (Distributed) **Main Document** **Certificate of Word Count** **Proof of Service**
Jun 18 2018	DISTRIBUTED for Conference of 6/21/2018.
Jun 25 2018	Petition GRANTED.
Jul 02 2018	Motion for an extension of time to file the briefs on the merits filed. **Main Document**
Jul 03 2018	**Motion to extend the time to file the briefs on the merits granted. The time to file the joint appendix and petitioner's brief on the merits is extended to and including August 23, 2018. The time to file respondents' brief on the merits is extended to and including October 9, 2018.**
Aug 01 2018	Blanket Consent filed by Petitioner, Helsinn Healthcare S.A..

	Blanket Consent
Aug 23 2018	Brief amicus curiae of Intellectual Property Owners Association in support of neither party filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Aug 23 2018	Brief of petitioner Helsinn Healthcare S.A. filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Aug 23 2018	Joint appendix filed. **Main Document** **Proof of Service**
Aug 23 2018	Brief amicus curiae of Congressman Lamar Smith filed. **Certificate of Word Count** **Proof of Service** **Main Document**
Aug 30 2018	Brief amicus curiae of The Massachusetts Biotechnology Council filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Aug 30 2018	Brief amicus curiae of United States of America filed. **Proof of Service** **Main Document**
Aug 30 2018	Brief amicus curiae of Pharmaceutical Research and Manufacturers of America filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Aug 30 2018	Brief amicus curiae of American Intellectual Property Law Association in support of neither party filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Aug 30 2018	Brief amicus curiae of Bar Association of the District of Columbia filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Aug 30 2018	Brief amicus curiae of Austin Intellectual Property Law Association in support of neither party filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Aug 30 2018	Brief amicus curiae of Houston Intellectual Property Law Association in support of neither party filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Aug 30 2018	Brief amicus curiae of The Naples Roundtable in support of neither party filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Aug 30 2018	Brief amicus curiae of The Intellectual Property Law Association of Chicago in support of neither party filed. **Main Document** **Proof of Service** **Certificate of Word Count**

Aug 30 2018	Brief amicus curiae of The Biotechnology Innovation Organization (BIO) filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Aug 30 2018	Brief amicus curiae of US Inventor, Inc. filed. **Main Document** **Proof of Service** **Certificate of Word Count**
Sep 24 2018	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed. **Proof of Service** **Main Document**
Oct 09 2018	SET FOR ARGUMENT on Tuesday, December 4, 2018
Oct 09 2018	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED. Justice Kavanaugh took no part in the consideration or decision of this motion.
Oct 09 2018	Brief amici curiae of 45 Intellectual Property Professors filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Oct 09 2018	Brief of respondents Teva Pharmaceuticals USA, Inc., et al. filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Oct 15 2018	Record requested from the U.S.C.A. Federal Circuit.
Oct 15 2018	Brief amici curiae of R Street Institute and Engine Advocacy filed. **Main Document** **Proof of Service** **Certificate of Word Count**
Oct 16 2018	Brief amicus curiae of Intel Corporation filed. **Main Document** **Proof of Service** **Certificate of Word Count**
Oct 16 2018	Brief amicus curiae of Congresswoman Zoe Lofgren filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Oct 16 2018	Brief amicus curiae of IEEE-USA filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Oct 16 2018	Brief amicus curiae of Association for Accessible Medicines filed. **Main Document** **Certificate of Word Count** **Proof of Service**
Oct 16 2018	Brief amici curiae of SPCM S.A. and High Tech Inventors Alliance filed. **Main Document** **Certificate of Word Count** **Certificate of Word Count**
Oct 19 2018	CIRCULATED

Oct 24 2018	Record received from the U.S.C.A. Federal Circuit is electronic and located on PACER, with the exception of some confidential documents (1 Envelope).
Nov 08 2018	Reply of petitioner Helsinn Healthcare S.A. filed. (Distributed) **Main Document** **Certificate of Word Count** **Proof of Service**
Dec 04 2018	Argued. For petitioner: Kannon K. Shanmugam, Washington, D. C.; and Malcolm L. Stewart, Deputy Solicitor General, Department of Justice, Washington, D. C. (for United States, as amicus curiae.) For respondents: William M. Jay, Washington, D. C.
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No.

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

CORPORATE DISCLOSURE STATEMENT

Petitioner Helsinn Healthcare S.A. is a subsidiary of Helsinn Holding S.A. Helsinn Holding S.A. has no parent corporation, and no publicly held company holds 10% or more of its stock.

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In the Supreme Court of the United States

No.

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

Helsinn Healthcare S.A. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 17a-52a) is reported at 855 F.3d 1356. The opinion of the district court (App., *infra*, 235a-241a) is unreported. The supplemental opinion of the district court (App., *infra*, 53a-231a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 1, 2017. A petition for rehearing was denied on January 16, 2018 (App., *infra*, 1a-16a). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

1. Section 3(b)(1) of the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, 285-286 (2011), provides:

> Section 102 of title 35, United States Code, is amended to read as follows:
>
> * * *
>
> (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
>
> > (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention[.]
>
> * * *
>
> (b) EXCEPTIONS.—
>
> > (1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—
> >
> > > (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or

> (B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

* * *

2. Section 3(a) of the AIA, 125 Stat. 285, provides:

> DEFINITIONS.—Section 100 of title 35, United States Code, is amended—
>
> * * *
>
> (2) by adding at the end the following:
>
> * * *
>
> (j) The term 'claimed invention' means the subject matter defined by a claim in a patent or an application for a patent.

* * *

STATEMENT

Yet again, the Federal Circuit has issued a decision that is "untethered to the statutory text" of the patent laws. *Limelight Networks, Inc.* v. *Akamai Technologies, Inc.*, 134 S. Ct. 2111, 2120 (2014). This case involves the Federal Circuit's interpretation of the Leahy-Smith America Invents Act (AIA), the most significant revision to our Nation's patent laws in more than half a century. As part of the transformative revisions in the AIA, Congress amended the definition of prior art, which identifies the universe of existing knowledge against which an invention's patentability is measured. The decision below involves a commonly litigated category of prior art: prior sales of an invention.

Under the AIA, an inventor is entitled to a patent unless "the claimed invention was * * * in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention." 35 U.S.C. 102(a)(1) (emphasis added). Critically, in amending the existing definition of prior art, Congress added the residual phrase "or otherwise available to the public." That phrase informs the meaning of the phrases that precede it, requiring that sales make the claimed invention "available to the public" to qualify as prior art. That was the expressed intent of the congressional committee that first introduced the residual phrase, as well as the AIA's sponsors. And it is how the Patent and Trademark Office (PTO) interprets the statute: the PTO adopted that interpretation in examination guidelines issued shortly after the AIA's enactment and reaffirmed it in an amicus brief supporting petitioner below.

Yet the Federal Circuit rejected the foregoing interpretation. In the decision below, it held that, under the AIA, public disclosure of the *existence* of a commercial sale invalidates a patent, even if the claimed invention itself remains secret and is not "available to the public"—a position that no party or amicus advocated. The Federal Circuit did not reach that decision by applying anything resembling the usual approach to statutory construction. Instead, it held that the floor statements of the AIA's sponsors were not sufficiently clear to abrogate the Federal Circuit's pre-AIA precedent—in part because the sponsors did not cite specific cases by name. Needless to say, that is not how courts are supposed to construe statutes. The Federal Circuit's flawed decision cries out for this Court's review.

The proper interpretation of the AIA's definition of prior art is critically important to the patent community and the PTO. The definition of prior art goes to the heart

of patentability, and the AIA's definition is a foundational building block of the first-inventor-to-file patent system that the AIA creates. The Federal Circuit's decision threatens to upend that carefully constructed system. Of particular relevance here, prospective patentees commonly enter confidential agreements such as the ones at issue in this case, and the securities laws often require disclosure of the existence of such agreements, particularly for smaller companies. The Federal Circuit's decision casts doubt on the validity of countless patents issued since the AIA took effect and will chill valuable collaborations by smaller innovators. The Court should grant review to restore the AIA's definition of prior art to its intended, plain-text meaning.

A. Background

1. As early as 1829, this Court held that an inventor's "voluntary act or acquiescence in the *public sale* and use" of his invention before the filing of a patent application is an "abandonment of his right." *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1, 24 (1829) (emphasis added). That long-standing principle of patent law, known as the "on-sale bar," stemmed from the law's "reluctance to allow an inventor to remove existing knowledge from public use." *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55, 64 (1998).

Before the AIA, the operative version of the on-sale bar was found in 35 U.S.C. 102(b), which provided that a patent could not issue if "the invention was patented or described in a printed publication in this or a foreign country or in public use or *on sale* in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. 102(b) (2006) (emphasis added). Applying that provision, this Court held that two conditions must be satisfied for the on-sale bar to apply: first, "the product must be the subject of a commercial offer for

sale," and, second, "the invention must be ready for patenting." *Pfaff*, 525 U.S. at 67.

With respect to the first of those conditions, the Federal Circuit held before the AIA that an inventor's secret sale of an invention to another party could constitute a "commercial offer for sale." See, *e.g.*, *Special Devices, Inc.* v. *OEA, Inc.*, 270 F.3d 1353, 1354, 1357 (Fed. Cir. 2001); *In re Caveney*, 761 F.2d 671, 675 (Fed. Cir. 1985). For example, in *Special Devices*, the Federal Circuit held that a patentee's contract with a supplier to produce and stockpile an invention was a disqualifying "sale," even if it occurred in "secret." 270 F.3d at 1354, 1357.

2. This case concerns the version of the on-sale bar adopted by Congress in the AIA. Enacted in 2011, the AIA significantly transformed our Nation's patent laws. *Kappos* v. *Hyatt*, 566 U.S. 431, 434 n.1 (2012). Most important among the AIA's reforms was the creation of a first-inventor-to-file patent system, which replaced the preexisting first-to-invent system. In the same provision of the AIA that created the first-inventor-to-file system, Congress amended the definition of prior art. Prior art is the foundation of existing knowledge against which an invention's novelty and nonobviousness are measured. As amended by the AIA, 35 U.S.C. 102(a), entitled "Novelty; prior art," provides that a person shall be entitled to a patent "unless * * * the claimed invention was patented, described in a printed publication, or in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention." 35 U.S.C. 102(a)(1) (emphasis added).[1]

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[1] Section 102(b) exempts from the definition of prior art certain disclosures made one year or less before the effective filing date of the claimed invention. That exemption is inapplicable in this case.

The AIA's definition of prior art differs from its pre-AIA counterpart in several important respects. *First*, Congress added the residual phrase "or otherwise available to the public" in the AIA, appending it to the preceding phrases "in public use" and "on sale." *Second*, Congress eliminated the pre-AIA territorial restriction requiring invalidating public uses or sales to occur "in this country." 35 U.S.C. 102(b) (2006). *Third*, Congress replaced the term "invention" with the phrase "claimed invention," and it defined "claimed invention" as "the subject matter defined by a claim in a patent or an application for a patent." 35 U.S.C. 100(j).

The legislative history confirms that Congress's intent in adding the residual phrase "or otherwise available to the public" was to eliminate "secret sales" as prior art and to require that the sale make the "claimed invention" "available to the public." See generally Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 466-475 (2011). The phrase originated in the Senate Judiciary Committee, which explained that it was adding the phrase to "emphasize the fact that [prior art] must be publicly available." S. Rep. No. 259, 110th Cong., 2d Sess. 9 (2008); accord S. Rep. No. 18, 111th Cong., 1st Sess. 6 (2009). After the Senate bill passed, the House Judiciary Committee considered a revised bill that became the AIA. That bill contained the same residual phrase, and the House Committee echoed the explanation that the phrase was intended to "emphasize the fact that [prior art] must be publicly accessible." H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. I, at 42-43 (2011); see *id.* at 43 n.20 (citing floor statements of the Senate sponsors).

Several of the AIA's sponsors reiterated the point in floor statements. Senator Kyl explained that the new residual phrase operated on the preceding phrases, thus

"limit[ing] all non-patent prior art to that which is available to the public." 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011). Senator Leahy, the AIA's lead sponsor in the Senate, similarly explained that the statute would "do away with precedent under current law that private offers for sale or private uses of secret processes * * * may be deemed patent-defeating prior art." 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011). The AIA's lead sponsor in the House, Representative Lamar Smith, agreed: "[C]ontrary to current precedent, in order to trigger the bar in the new [Section] 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date." 157 Cong. Rec. H4429 (daily ed. June 22, 2011).

3. Following the AIA's enactment, the PTO issued revised guidelines for examining patent applications. See 78 Fed. Reg. 11,059 (Feb. 14, 2013). Of particular relevance here, the PTO instructed its examiners that, under the AIA, a sale "must make the invention available to the public" to be prior art. *Id.* at 11,075. Under that interpretation, the PTO explained, sales "among individuals having an obligation of confidentiality to the inventor" do not constitute prior art under the AIA. *Ibid.* The PTO later incorporated its interpretation into the Manual of Patent Examining Procedures (MPEP). See MPEP § 2152.02(d) (9th ed. 2014) (stating that "[t]he 'or otherwise available to the public' residual clause of * * * 35 U.S.C. 102(a)(1) [as amended] * * * indicates that [it] does not cover secret sales or offers for sale").

B. Facts And Procedural History

1. Petitioner is a small, family-owned pharmaceutical company based in Switzerland. Petitioner focuses on supportive care for cancer patients through the research, de-

velopment, and production of innovative products that improve patients' health and quality of life. This case involves petitioner's flagship drug, Aloxi®, a pathbreaking treatment for cancer patients suffering from chemotherapy-induced nausea and vomiting. C.A. App. 516, 594-595, 1176-1777.

The active pharmaceutical ingredient in Aloxi is palonosetron. Petitioner acquired the rights to palonosetron in 1998. In 2000, petitioner submitted protocols for Phase III clinical trials to the Food and Drug Administration (FDA), proposing to study two dosages of palonosetron (0.25 mg and 0.75 mg). Petitioner, which had never before sought approval for a drug product in the United States, underestimated the costs of developing Aloxi. As a result, the project was in danger of being terminated. To sustain the project and defray costs, petitioner sought a business partner. App., *infra*, 22a; C.A. App. 597, 608, 918.

In 2001, petitioner entered a license agreement and a supply and purchase agreement with MGI Pharma, a small Minnesota company. Under the agreements, MGI agreed to make upfront payments, and to pay future royalties if petitioner's products obtained FDA approval. The agreements described the potential products then being tested, including the 0.25 and 0.75 mg palonosetron doses. MGI agreed to purchase from petitioner whichever palonosetron product, if any, FDA approved. The agreements bound MGI to keep confidential petitioner's proprietary knowledge related to the products, including the proposed novel formulations. App., *infra*, 22a-23a; C.A. App. 608, 1516.

MGI was a public company, and it filed a Form 8-K with the Securities and Exchange Commission disclosing the agreements. While MGI attached the agreements to

the filing, it redacted the covered palonosetron formulations, consistent with its contractual obligation of confidentiality to petitioner. Petitioner and MGI simultaneously announced the agreements in a press release, again omitting the details of the palonosetron formulations. App., *infra*, 22a-24a.

In 2002, after the successful completion of Phase III clinical trials, petitioner submitted a new drug application to FDA for the 0.25 mg dose. FDA approved the application in July 2003. App., *infra*, 25a.

In 2003, petitioner filed a provisional (*i.e.*, preliminary) patent application covering the 0.25 mg dose. See 35 U.S.C. 111(b). Petitioner then filed a series of further applications claiming priority to the 2003 provisional application, culminating in a 2013 application that issued as U.S. Patent No. 8,598,219 (the '219 patent). See 35 U.S.C. 119(e). That patent is listed in FDA's Orange Book and expires in 2024. It is undisputed that, by virtue of its effective application date, the patent is governed by the AIA. App., *infra*, 19a, 25a, 234a.[2]

2. In 2011, respondents filed an abbreviated new drug application (ANDA) seeking FDA approval to market a generic version of petitioner's 0.25 mg palonosetron product. Respondents' ANDA included a so-called "Paragraph IV" certification that petitioner's patents were invalid or would not be infringed by respondents' generic version. Pursuant to the Hatch-Waxman Act, petitioner commenced a patent-infringement action against respondents in the United States District Court for the District of New Jersey. App., *infra*, 26a.

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[2] This case also involved three other patents governed by the pre-AIA on-sale bar. Although petitioner disagrees with the Federal Circuit's determination that the pre-AIA on-sale bar invalidates those patents, see App., *infra*, 27a-34a, petitioner is not seeking review of that determination here.

After a bench trial, the district court held that petitioner's patent was valid and would be infringed by respondents' generic version. App., *infra*, 233a-234a. Of relevance here, the court rejected respondents' argument that petitioner's agreements with MGI invalidated the '219 patent under the AIA's on-sale bar. *Id.* at 164a, 180a. According to the court, the AIA requires that the sale make the claimed invention available to the public; the redacted agreements did not disclose petitioner's claimed palonosetron formulation and thus did not make it publicly available. *Ibid.* The district court enjoined respondents from manufacturing or selling their generic version of Aloxi until the expiration of petitioner's patent in 2024. *Id.* at 234a.

3. Respondents appealed to the Federal Circuit. Notably, respondents did not argue that the MGI agreements made Helsinn's invention "available to the public"; they conceded that "the allegedly invalidating sale at issue did not make the invention publicly available." Gov't C.A. Br. 2-3. Respondents offered only the legal argument that, under the AIA, the residual phrase "or otherwise available to the public" does not inform the meaning of the preceding phrase "on sale." See Resp. C.A. Br. 51-55; but see Pet. C.A. Br. 34-36 (arguing to the contrary).

The government filed a brief as amicus curiae in support of petitioner. Reaffirming petitioner's arguments and the PTO's guidance to patent examiners, the government stated that "[t]he plain text of section 102(a)(1) makes clear that only sales or offers for sale that make an invention 'available to the public' trigger the on-sale bar, and the purpose and structure of the AIA support that plain-text reading." Gov't C.A. Br. 4 (citation omitted). The government also participated in oral argument as amicus curiae. Five other amici, including Representative Smith, likewise endorsed petitioner's reading.

4. The Federal Circuit reversed. App., *infra*, 17a-52a.

In its opinion, the Federal Circuit did not resolve the parties' competing interpretations of the statute; it did not consult the AIA's statutory definitions; and it did not apply the traditional tools of statutory construction. Instead, the court surveyed a selection of the floor statements of the AIA's sponsors. App., *infra*, 34a-43a. As discussed above, those floor statements, as well as the Senate and House committee reports, addressed the on-sale bar and explained that the AIA would require that the claimed invention be "available to the public" to defeat patentability. See pp. 7-8, *supra*. The Federal Circuit, however, observed that the only cases "explicitly referenced" by name by the AIA's sponsors involved the "in public use" bar. App., *infra*, 38a. According to the court, "[t]he floor statements do not identify any *sale* cases that would be overturned by the amendments." *Ibid.* On that basis, the court implied that the AIA had no effect on the on-sale bar. *Ibid.*

Notwithstanding that implication, the Federal Circuit went on to state that, "[e]ven if the floor statements were intended to overrule [the court's] secret or confidential sale cases[,] * * * that would have no effect here since those cases were concerned entirely with whether the *existence* of a sale or offer was public." App., *infra*, 38a (emphasis added). The court asserted that it had held before the AIA's enactment that the on-sale bar was satisfied where "there is a commercial offer or contract to sell a product embodying the invention and that sale is made public," regardless of whether "the details of the invention [were] disclosed in the terms of sale." *Id.* at 40a. The court found no clear indication in the floor statements that Congress intended to abrogate that precedent. *Id.* at 43a.

The Federal Circuit thus concluded that, "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of the sale"—even if, as here, the counterparty was required to keep those details confidential. App., *infra*, 43a. Applying that interpretation, the court determined that, because the existence of the agreements between petitioner and MGI was publicly known, the agreements invalidated petitioner's patent. *Id.* at 43a, 52a.[3]

5. Petitioner filed a petition for rehearing. Six amici, including Representative Smith, supported the petition. More than six months after the petition was filed, the Federal Circuit denied rehearing. App., *infra*, 2a.

In an apparent effort to mitigate the damage done by the Federal Circuit's opinion, Judge O'Malley, a member of the original panel, issued an opinion concurring in the denial of rehearing that one commentator has described as a "judicial brief in opposition." Scott Graham, *(On-Sale) Bar Fight Heads to SCOTUS*, Law.com (Jan. 25, 2018) <tinyurl.com/on-sale-bar-fight>; see App., *infra*, 3a-16a. Judge O'Malley sought to portray the Federal Circuit's opinion as narrow, contending that the court had held only that "the *particular* agreement at issue triggered the on-sale bar, in part—but not exclusively—because it was made public." App., *infra*, 5a. At the same time, Judge O'Malley categorically stated that the court had "correctly concluded that the AIA did not change longstanding precedent governing the on-sale bar." *Id.* at 3a-4a. In the wake of the court's failure to analyze the

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[3] The Federal Circuit also determined that petitioner's invention satisfied the second condition of the on-sale bar: namely, that the invention was ready for patenting. App., *infra*, 43a-52a. Petitioner is not seeking review of that determination.

AIA's text in reaching its conclusion, Judge O'Malley proceeded to supply her own textual analysis, which largely adopted respondents' arguments. *Id.* at 8a-11a.

Judge O'Malley concluded by acknowledging that "[i]t is fair to question whether * * * distribution agreements [such as the agreements at issue] *should* fall within the scope of the on-sale bar," and she observed that the existing rule has long provoked criticism. App., *infra*, 15a-16a. Notwithstanding that Congress had amended Section 102 in the AIA, Judge O'Malley stated that, "[u]ntil Congress amends § 102 to exclude such agreements from its scope, or the Supreme Court changes the analysis we are to employ when considering such transactions, these criticisms will continue." *Id.* at 16a.

REASONS FOR GRANTING THE PETITION

This case presents a question of exceptional importance to the patent community and the Patent and Trademark Office. The identification of prior art is a critical component of patent examination and litigation because of the central role of prior art in determining the validity of patents. Accordingly, stakeholders at all levels of the patent process need to have a clear and accurate understanding of which sales of an invention qualify as prior art.

Without this Court's guidance, the patent community will have no choice but to attempt to apply a Federal Circuit decision that is deeply flawed both in its reasoning and in its outcome. The Federal Circuit purported to construe the AIA without actually analyzing its text. The Federal Circuit's rule has no basis in the text; indeed, no party or amicus even argued for it. And the Federal Circuit rejected the position of the PTO, as codified in examination guidelines that have governed the issuance of more than one million patents. This Court should grant

certiorari to review and reverse the Federal Circuit's misinterpretation of a critical provision of the patent laws.

A. The Decision Below Is Erroneous

As the government observed below, the text, structure, and history of the AIA unequivocally support the conclusion that "an invention is only 'on sale' under the AIA if the sale or offer for sale makes the invention 'available to the public.'" Gov't C.A. Br. 1. The Federal Circuit's contrary holding was the result of a profoundly flawed analysis. The Court should grant review to correct the Federal Circuit's indefensible interpretation.

1. The Decision Below Is Inconsistent With The Statutory Text

By its plain terms, the AIA requires that a sale make an invention "available to the public" in order to qualify as prior art.

a. As amended by the AIA, 35 U.S.C. 102(a)(1) provides that "[a] person shall be entitled to a patent unless * * * the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." As the PTO and the AIA's sponsors have recognized, the AIA's text and structure demonstrate that the phrase "otherwise available to the public" clarifies the scope of the preceding phrase "on sale."

i. Section 102(a)(1) identifies five categories of prior art. The first two—patents and printed publications—are, by their very nature, publicly available. Following the intervening word "or," the statute identifies a series of three additional categories: claimed inventions that are "in public use, on sale, or *otherwise* available to the public." 35 U.S.C. 102(a)(1) (emphasis added).

That final series—"in public use, on sale, or otherwise available to the public"—has a familiar structure. It consists of "several [phrases] * * * followed by a [phrase] which is applicable as much to the first and other words as to the last." *Paroline* v. *United States*, 134 S. Ct. 1710, 1721 (2014) (citation omitted). Where that is the case, "the natural construction of the language demands that the [phrase] be read as applicable to all." *Ibid.* (citation omitted); see also Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 147-151 (2012) (discussing the series-modifier canon). Put another way, the final "catchall" phrase identifies a defining characteristic of all of the categories of prior art identified in the series, *Paroline*, 134 S. Ct. at 1721 (citation omitted): they make the claimed invention "available to the public."

Congress's choice of the word "otherwise" in the final phrase confirms that reading of the statute. "Otherwise" means "in a different way or manner." *Merriam-Webster's Collegiate Dictionary* 879 (11th ed. 2005). By using that word, Congress made clear that prior art consists of (1) sales or public uses that make the claimed invention "available to the public," as well as (2) other actions that make the claimed invention "available to the public" "in a different way or manner." Any other reading of the three-part series would render the word "otherwise" superfluous. See *United States* v. *Menasche*, 348 U.S. 528, 538-539 (1955). This Court has applied identical logic to a similar statute to reach the same result. See *United States* v. *Standard Brewery, Inc.*, 251 U.S. 210, 218 (1920) (rejecting the government's position that a statute prohibiting "beer, wine, or other intoxicating malt or vinous liquor for beverage purposes" encompassed all "beer and wine whether intoxicating or not").

ii. In the proceedings below, respondents argued that a "limiting clause" like the one in section 102(a)(1) "normally only applies to the 'last antecedent.'" Resp. C.A. Br. 4, 52-54 (quoting *Barnhart* v. *Thomas*, 540 U.S. 20, 26 (2003)). By that logic, respondents urged, the phrase "to the public" modifies only "otherwise available" and not the words before it. See *ibid.*

The relevant issue, however, is not whether "to the public" modifies "otherwise available" (it does), but whether the *whole phrase* "or otherwise available to the public" informs the meaning of the two parallel phrases that precede it (again, it does). In *Paroline*, this Court applied the series-modifier canon to reject a materially identical argument based on the last-antecedent rule, noting that the argument would have "require[d] accepting unlikely premises." 134 S. Ct. at 1721 (internal quotation marks and citation omitted).

The other textual arguments advanced by respondents (and by Judge O'Malley in her opinion concurring in the denial of rehearing) fare no better. *First*, respondents argued that interpreting the phrase "or otherwise available to the public" as informing the meaning of the preceding phrases creates redundancy because the phrase "in public use" already includes the word "public." Resp. C.A. Reply Br. 16-18; see App., *infra*, 8a n.2. But that argument overlooks that, before the AIA, the Federal Circuit had interpreted the phrase "in public use" to include certain types of secret uses. See App., *infra*, 37a-38a. It thus makes perfect sense that Congress intended for the phrase "or otherwise available to the public" to bear on the meaning of the phrase "in public use" (as well as the

phrase "on sale").[4] Judge O'Malley further contended that petitioner's interpretation conflates "on sale" with "public use," App., *infra*, 10a, but "uses" and "sales" may make an invention available to the public in different ways, preserving separate meaning for those terms.

Second, respondents argued that petitioner's interpretation of Section 102(a)(1) conflicts with an exemption in Section 102(b)(1) for certain disclosures made less than one year before a patent's effective filing date. Resp. C.A. Br. 55-58; see App., *infra*, 10a-11a (O'Malley, J., concurring in the denial of rehearing). According to respondents, Congress's use of the term "disclosure" in Section 102(b)(1)(A), contrasted with its use of the phrase "public[] disclos[ure]" in Section 102(b)(1)(B), necessarily means that some prior art in Section 102(a)(1) is not available to the public.

As the government and Representative Smith argued below, that argument misunderstands Section 102(b)(1). See Gov't C.A. Br. 21-23; Rep. Smith C.A. Br. 3-16. Section 102(b)(1) provides that certain disclosures that would otherwise be prior art will not disqualify a patent if they are made within the one-year period before the patent's effective filing date. The provision identifies two different categories of disclosures that will not disqualify a patent.

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[4] In a similar vein, Judge O'Malley suggested that petitioner's interpretation creates "redundancies" with the other categories of prior art in Section 102(a)(1)—namely, patents and printed publications. App., *infra*, 8a n.2. That suggestion overlooks the structure of Section 102(a)(1). The residual phrase informs the meaning only of the phrases "in public use" and "on sale"; the other forms of prior art in Section 102(a)(1) stand apart from the final three-item series. And even if the residual phrase operates on all the forms of prior art in Section 102(a)(1), the presence of some terms that are always consistent with that phrase does not rob the phrase of its limiting effect upon other terms, including "on sale."

Section 102(b)(1)(A) exempts "disclosure[s]" that meet the requirements of Section 102(a)(1)—*i.e.*, that satisfy the definition of prior art—and were made by an inventor (or someone who obtained the subject matter from an inventor). In other words, once an inventor makes a disclosure that qualifies as prior art, the inventor has one year to submit a patent application. Congress had no need to use the term "public" to describe those disclosures, because all prior art under Section 102(a)(1) is necessarily available to the public.

The exemption in Section 102(b)(1)(A) is limited to prior-art disclosures by, or derived directly from, the inventor; prior-art disclosures by *third parties* within that one-year period are not exempt as a general matter. Section 102(b)(1)(B) creates a limited exception to that rule. If the inventor "publicly disclose[s]" his invention, subsequent disclosures within the one-year period that meet the requirements of Section 102(a)(1) will be exempt, regardless of who makes the disclosure. Again, as in Section 102(b)(1)(A), Congress did not use the word "publicly" to describe the disclosures subject to the exemption. To the contrary, the words "publicly disclosed" in Section 102(b)(1)(B) refer to a different, antecedent disclosure: when an inventor publicly discloses the subject matter of an invention, he is entitled to "a one-year grace period, starting on the date [he] discloses an invention to the public, during which even disclosures of the same invention by third parties will not be deemed patent-defeating prior art." Gov't C.A. Br. 22. Congress's use of the term "public[]" in that provision does nothing to undermine the proposition that

all Section 102(a)(1) prior art must be "available to the public."[5]

b. In construing Section 102(a)(1), the Federal Circuit did not apply the traditional tools of statutory interpretation. It barely discussed the text of the provision, and it altogether ignored the AIA's definition of the term "claimed invention." Instead, the Federal Circuit parsed legislators' floor statements for indications of a specific intent to abrogate its pre-AIA decisions, which had construed materially different statutory text. See pp. 12-13, *supra*.

To say the least, that is not an acceptable approach to statutory interpretation. "[T]he authoritative statement" of the law is "the statutory text, not the legislative history or any other extrinsic material." *Exxon Mobil Corp.* v. *Allapattah Services, Inc.*, 545 U.S. 546, 568 (2005). Patent law is not subject to different rules: as in all statutory-interpretation cases, courts interpreting the patent laws must "look first to the text of the statute." *Life Technologies Corp.* v. *Promega Corp.*, 137 S. Ct. 734, 739 (2017).

The court of appeals departed from that principle by turning directly to portions of the legislative history. See, *e.g.*, App., *infra*, 37a-38a (analyzing whether "the floor statements were intended to overrule * * * secret or confidential sale cases"). This Court has famously cautioned that "[j]udicial investigation of legislative history has a tendency to become * * * an exercise in looking over a crowd and picking out your friends." *Exxon Mobil*, 545 U.S. at 568 (internal quotation marks and citation

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[5] By contrast, Section 102(a)(2)—which identifies patent *applications* as prior art—encompasses certain non-public prior art. See Gov't C.A. Br. 21-22; Rep. Smith C.A. Br. 4-5. The fact that an inventor's "disclosures" could include non-public prior art further explains Congress's choice of the word "publicly" in Section 102(b)(1)(B). See Gov't C.A. Br. 22.

omitted). But here, there were no friends to be found: the committee reports and floor statements unambiguously support petitioner's interpretation. See pp. 7-8, *supra*. The Federal Circuit thus resorted to picking apart the floor statements of the AIA's sponsors, faulting them for an insufficiently clear statement of intent to abrogate specific Federal Circuit precedents.

The Federal Circuit first implied that the AIA has no effect on the scope of the on-sale bar simply because its sponsors did not cite cases involving the on-sale bar by name. App., *infra*, 37a-38a; see *id.* at 3a-4a (O'Malley, J., concurring in the denial of rehearing) (stating that "the panel correctly concluded that the AIA did not change longstanding precedent governing the on-sale bar"). Unsurprisingly, the Federal Circuit did not cite any precedent requiring an act's sponsors to cite the Federal Reporter in order to change the law. That suggestion is at best bizarre and at worst betrays a reluctance on the part of the Federal Circuit to recognize congressional abrogation of its precedent, even when Congress alters the very statutory provision the Federal Circuit was previously construing.

In a similar vein, the Federal Circuit dismissed statements showing an intent to eliminate secret sales as prior art, on the ground that they did not demonstrate with sufficient clarity an intent to abrogate pre-AIA precedent holding that a sale occurs for purposes of the on-sale bar even when the details of the invention are not "disclosed in the terms of sale" or when delivery of the product does not occur. App., *infra*, 39a-43a. Finding no floor statements evincing Congress's intent to overrule those cases, the court concluded that, "if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." *Id.* at 43a.

Again, however, the statutory text is the paramount evidence of congressional intent. See p. 20, *supra*. And in any event, many of the pre-AIA cases cited by the Federal Circuit may be consistent with the AIA's requirement that a sale make the claimed invention "available to the public." 35 U.S.C. 102(a)(1). As the Federal Circuit explained, many of those cases were based on the rationale that "publicly offering a product for sale that embodies the claimed invention places it in the public domain." App., *infra*, 42a. This case does not involve a sale to the public or a product in the public domain. It involves a secret sale—that is, a sale to a party with an obligation of confidentiality to the inventor—and, as respondents conceded below, nothing about that sale or the disclosure of the fact of the sale made the "claimed invention" "available to the public." 35 U.S.C. 102(a)(1); see p. 11, *supra*.[6]

As a result of its flawed approach, the Federal Circuit all but ignored the statutory phrase "claimed invention." The court concluded that a commercial sale can be prior art when the *fact* of a sale is "publicly disclosed." App., *infra*, 42a-43a. But the AIA does not require that the fact of a sale be made available to the public. It requires that the "*claimed invention*" be made available. 35 U.S.C. 102(a)(1) (emphasis added). Under the AIA, a "claimed invention" is "the subject matter defined by a claim in a patent or an application for a patent." 35 U.S.C. 100(j). The Federal Circuit completely ignored that definition, and its decision effectively reads the words "claimed invention" out of the statute.

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[6] In her opinion concurring in the denial of rehearing, Judge O'Malley stated that the MGI agreements "described the claimed drug formulation in detail." App., *infra*, 5a (internal quotation marks and citation omitted). But the "claimed invention"—*i.e.*, the drug formulation—was redacted from the publicly disclosed agreements and thus was not available to the public, as respondents conceded.

By contrast, petitioner's interpretation of Section 102(a)(1) affords the phrase "claimed invention" the meaning the AIA provides. When an inventor sells its invention to a party that is required to keep the invention confidential, the "subject matter" of the patent claims is not "available to the public," even if the public learns of the fact of the sale.

2. The Decision Below Is Inconsistent With The Broader Statutory Structure

a. The broader statutory scheme further supports petitioner's interpretation. In the AIA, Congress moved the United States to a first-inventor-to-file system in order to "harmoniz[e]" the United States "with the patent systems commonly used in nearly all other countries throughout the world." AIA § 3(p), 125 Stat. 293; see H.R. Rep. No. 98, *supra*, Pt. I, at 39. Congress's elimination of secret prior art is part of that harmonization effort. As the government explained below, "[n]o other industrialized nation includes secret sales within the prior art." Gov't C.A. Br. 10 (citing Dmitry Karshtedt, *Did Learned Hand Get It Wrong?: The Questionable Patent Forfeiture Rule of 'Metallizing Engineering,'* 57 Vill. L. Rev. 261, 316 (2012)). For example, mirroring the language chosen by Congress in the AIA, the European Patent Convention provides that "[t]he state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application." European Patent Convention, Art. 54(2), Oct. 5, 1973, 13 I.L.M. 268. If allowed to stand, the Federal Circuit's decision will mean that the United States will once again stand alone in invalidating patents based on secret "prior art."

b. In addition, Congress's creation of a first-inventor-to-file system informs many of the other revisions in the AIA, including the revision to the definition of prior art. Before the AIA, patentability hinged on who first invented something, rather than who first applied to patent it. Consistent with that fact, the law recognized certain categories of "secret" prior art. For example, a patent could not issue if another person had invented the invention before the relevant priority date, even if the invention was not then available to the public. See 35 U.S.C. 102(g) (2006); *OddzOn Products, Inc.* v. *Just Toys, Inc.*, 122 F.3d 1396, 1401-1404 (Fed. Cir. 1997). It is uncontested that the AIA abolished several categories of "secret" prior art, such as the one just discussed.

Congress's revision of the on-sale bar should be understood in that context. Before the AIA, the on-sale bar operated to prevent *de facto* patent-term extensions. Under a first-to-invent system, inventors had an incentive to profit from their inventions for as long as possible without disclosing them; if a competitor later sought to patent the same invention, the original inventor could claim priority. The on-sale bar, as construed by the Federal Circuit, thus motivated inventors to enter the patent system within the one-year grace period.

But under the AIA's first-inventor-to-file system, no such motivation is needed. An inventor cannot secretly exploit its invention while waiting for competition to come along because the competition might beat the first inventor to the Patent Office. Limiting the on-sale bar to sales that make the invention publicly available thus goes hand-in-hand with the AIA's first-inventor-to-file system, as Senator Kyl explained. See 157 Cong. Rec. S1370-S1371 (daily ed. Mar. 8, 2011); Gov't C.A. Br. 11-12. The Federal Circuit's decision ignores that statutory framework.

c. The Federal Circuit's interpretation also creates anomalies in light of Congress's decision to eliminate territorial restrictions on prior art, including the on-sale bar. As discussed above, in the AIA, Congress deleted language that previously restricted disqualifying sales to those occurring in the United States. See p. 7, *supra*; 35 U.S.C. 102(b) (2006). That undisputed geographic expansion demonstrates the error in Judge O'Malley's assertion that "Congress meant to leave the on-sale bar intact." App., *infra*, 9a. If allowed to stand, the Federal Circuit's decision will have the perverse effect of expanding the on-sale bar to include secret sales occurring outside the United States despite clear statutory language designed to limit it. That anomaly is further proof that the Federal Circuit's interpretation is incorrect.

d. Finally with regard to the statutory structure, the Federal Circuit's interpretation is inconsistent with the AIA's creation of a procedure for post-grant review. See 35 U.S.C. 321-329. Congress designed post-grant review to provide a "more efficient system for challenging patents that should not have issued," H.R. Rep. No. 98, *supra*, Pt. I, at 39-40, and Congress limited discovery in such proceedings to further that end. As the government explained below, "invalidity challenges based on secret prior art are entirely unsuited to adjudication in these expedited proceedings." Gov't C.A. Br. 9; see 157 Cong. Rec. S1371 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl). Whether the fact of the sale is secret, or the fact of the sale is public but the content of the sale is secret, proving a "secret sale" requires burdensome discovery not contemplated by post-grant review. Congress's limitation of post-grant review to AIA patents therefore makes perfect sense under petitioner's interpretation, but not the Federal Circuit's.

3. The Decision Below Is Inconsistent With The Functions Of Prior Art And The On-Sale Bar In The Patent System

The Federal Circuit's holding is also at odds with the fundamental policy rationale of the patent system—a rationale that underlies both the concept of prior art more generally and the on-sale bar in particular.

"The basic quid pro quo * * * for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility." *Brenner* v. *Manson*, 383 U.S. 519, 534 (1966). A patent grant represents a fair trade. The public gives monopoly rights and prices to the patentee; in exchange, the patentee gives the public disclosure of a new and useful invention. If the patentee tried to give the public something it already had, the public would not receive the benefit of its bargain: it would forfeit its right to free and unrestricted use of an idea without receiving anything in return. See *Pennock*, 27 U.S. (2 Pet.) at 23.

To ensure that the public does not give away something in exchange for nothing, the law permits patents only on inventions that are both novel and nonobvious. See 35 U.S.C. 102 (novelty); 35 U.S.C. 103 (nonobviousness). Together, the novelty and nonobviousness requirements prohibit patents on anything that "is already available to the public or * * * which may be readily discerned from publicly available material." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989). To ascertain whether a patent application discloses something that was not "already available to the public," the patent system needs a practical way of expressing what the public already has. The concept of "prior art" serves that function. See *id.* at 148-150.

The definition of prior art is appropriately guided by its function—namely, to define what is in the public domain. For example, courts evaluate printed publications for prior-art status based on whether they were sufficiently accessible to the public as of the relevant date, reasoning that the publication bar "is grounded on the principle that once an invention is in the public domain, it is no longer patentable by anyone." *In re Hall*, 781 F.2d 897, 898-899 (Fed. Cir. 1986). This Court has described the rationale for the on-sale bar in similar terms, noting that "reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar." *Pfaff*, 525 U.S. at 64.

The Federal Circuit's interpretation of the AIA ignores the functions of prior art and the on-sale bar in the patent system. The sale of an invention to a party that is obligated to keep it secret does not place the invention in the public domain, even if the public learns of the fact of the sale. The issuance of a patent protecting such an invention thus does not "remove existent knowledge from the public domain." *Graham* v. *John Deere Co.*, 383 U.S. 1, 6 (1966); see Gov't C.A. Br. 18-21.

4. The Decision Below Is Inconsistent With The Legislative History

Although the Court need not consult the legislative history to decide the question presented, that history overwhelmingly supports the conclusion that the AIA's on-sale bar does not cover sales to parties having an obligation of confidentiality to the inventor. Neither the Federal Circuit nor Judge O'Malley even acknowledged the Senate and House reports, both of which state that the residual phrase was added to "emphasize the fact that [prior art] must be publicly accessible." H.R. Rep. No. 98, *supra*, Pt. I, at 42-43; accord S. Rep. No. 18, *supra*, at 6. And

the AIA's sponsors—including Representative Smith, who filed amicus briefs supporting petitioner below at the merits and rehearing stages—likewise made their intentions clear. See p. 7, *supra*.[7]

The legislative history thus confirms that the Federal Circuit's interpretation is profoundly flawed. The Court should grant certiorari to review and correct that interpretation.

B. The Question Presented Is Exceptionally Important And Warrants Review In This Case

1. Whether and when a transaction triggers the on-sale bar is a question of exceptional importance to the entire patent community. Prior art is a foundational concept of patent law, see pp. 26-27, *supra*, and inventors, the PTO, and the public must be able to define its boundaries with accuracy. The on-sale bar, in particular, "is probably the greatest source of litigation involving * * * challenges to patent validity" involving the definition of prior art. Janice M. Mueller, *Patent Law* 263 (5th ed. 2016). The Federal Circuit's interpretation, under which public reference to the fact of a sale can invalidate a patent even if the claimed invention is not *available* to the public, has created significant uncertainty for stakeholders at all stages of the patent process and warrants this Court's immediate review.

a. The decision below has significant implications for the more than one million patent holders who have been

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[7] Although Judge O'Malley dismissed certain floor statements as "statements by individual Senators made the day after the bill was passed," App., *infra*, 11a n.4, in fact Senator Kyl and Representative Smith both spoke *before* passage of the bills in their respective chambers, and all of the floor statements preceded the vote in both chambers on the final House bill that was enacted.

granted patents since the PTO issued its post-AIA guidance in 2012. As discussed above, the PTO's post-AIA guidelines provide that a sale "must make the invention available to the public" to satisfy the on-sale bar, and further provide that sales "among individuals having an obligation of confidentiality to the inventor" do not constitute prior art under the AIA. 78 Fed. Reg. at 11,075; see p. 8, *supra*. Petitioner's agreements with MGI fall squarely within the PTO's definition of "secret"—again, a fact that respondents did not dispute below—but the Federal Circuit's interpretation directly contradicts the agency's guidance. The Federal Circuit's decision thus casts substantial doubt on countless patents issued pursuant to that guidance since the AIA.

Prospectively, absent clarification from this Court, the PTO must consider how to revise its instructions to its examiners. And examiners will now bear the substantial burden of conducting searches for prior art that include public references to the existence of otherwise secret sales, which may contain no indication on their face that they implicate the claimed invention. The PTO—which has already stated its position on the question presented—thus has a strong and urgent interest in the prompt resolution of that question by this Court. See Pranay Pattani & Thomas Kelton, *The On-Sale Bar And USPTO Practices After 'Helsinn,'* Law360 (May 30, 2017) (noting that the decision below "places the [PTO] in the difficult position of deciding whether to continue to apply its stated position or whether to change its position to align with the Federal Circuit in the near term").

b. The Federal Circuit's interpretation of the on-sale bar has particular significance for small innovators such as petitioner. As the history of this case illustrates, drug discovery is expensive and unpredictable. Even large pharmaceutical firms enter development partnerships to

share risk and defray cost. But small firms often have no choice, because they lack the resources to develop and bring a drug to market on their own. See PhRMA C.A. Br. 22-23. And as Judge O'Malley observed, "there is often a need to make distribution agreements public to induce investors to supply funding for product development." App., *infra*, 15a (opinion concurring in the denial of rehearing).

Under the Federal Circuit's interpretation, any public reference to such a partnership could defeat patentability, depending on the structure or timing of the transaction. And small public firms may find that such disclosure is outside their control: a given development partnership is more likely to be material under the securities laws, and thus subject to mandatory disclosure, for a small firm than for a large one. Thus, small firms are both more likely to require partners and more likely to have to disclose them than their larger counterparts.

At a minimum, then, the Federal Circuit's decision has the "potential to chill deals between small bio/pharma companies and potential commercialization partners." Andrew D. Cohen & Irena Royzman, *The Federal Circuit's First Application of the AIA's On-Sale Bar: Implications for Bio/Pharma*, Biologics Blog (May 16, 2017) <tinyurl.com/biologicsblog>. At worst, it will prevent small firms from bringing new drugs such as Aloxi to market altogether.

If that is the case, inventors will not be the only ones to suffer. The public substantially benefits from drugs such as Aloxi, and Aloxi's history demonstrates that it would not be on the market without the perseverance of small firms—and the contractual arrangements between them. The molecule was discovered by a small company (Syntex), which was bought by a large company (Roche) that promptly deemed the project too risky. App., *infra*,

75a. Roche divested the molecule to a second small company (petitioner), which sought a development partner. *Id.* at 75a-77a, 81a-82a. Ultimately, a third small firm (MGI) agreed to share petitioner's risk, providing the funding that allowed Aloxi to come to market, dramatically improving the quality of life of cancer patients. The Federal Circuit's decision threatens to complicate and impede such risk-sharing.

c. Given those practical consequences, it is unsurprising that this case has attracted substantial attention. The United States, Representative Smith, industry groups, academics, and other interested individuals filed amicus briefs at the merits stage in the Federal Circuit, and many of those amici supported petitioner's petition for rehearing en banc. The participation of these amici in the proceedings below confirms the importance of this case to stakeholders throughout the patent community.

In the wake of the Federal Circuit's decision, moreover, academics and other commentators have emphasized the issue's importance. Donald Chisum, the author of a venerable treatise on patent law, described the decision as "hugely significant." Michael Loney, *Federal Circuit Issues Important Helsinn On-Sale Bar Ruling*, Managing Intellectual Property (May 2, 2017). Janice Mueller, another patent-law scholar, agreed. See *ibid.* And many others have discussed and analyzed the opinion at length. See, *e.g.*, *ibid.*; Graham, *supra*; Lawrence E. Ashery, *The Risk of Losing Patent Rights When an Invention Is 'On Sale,'* Legal Intelligencer (May 23, 2017); Warren Woessner, *Federal Circuit in 'Helsinn v. Teva' Declines Limiting Requirements of 'On Sale' Bar*, Nat'l L. Rev. (May 4, 2017); Jerry Selinger, *Pre- And Post-AIA On-Sale Bar After 'Medicines' and 'Helsinn,'* Law360 (May 2, 2017).

2. This case is an ideal vehicle to decide the question presented. In the decision below, the Federal Circuit squarely held that the on-sale bar applies when the existence of a commercial sale is publicly disclosed, whether or not the disclosure made the claimed invention available to the public. App., *infra*, 43a. That holding is case-dispositive, and (given respondent's concession below) there is no factual dispute that would prevent the Court from resolving the pure question of statutory interpretation that this case presents.

Nor is there any colorable possibility of a circuit conflict in light of the Federal Circuit's exclusive jurisdiction over appeals relating to patents. The Federal Circuit's decision will remain the controlling interpretation of Section 102(a)(1)'s on-sale bar unless and until this Court considers the question. This Court has frequently intervened in recent years to correct the Federal Circuit's aberrant interpretations of the patent laws. See, *e.g.*, *Samsung Electronics Co.* v. *Apple Inc.*, 137 S. Ct. 429, 435-436 (2016); *Halo Electronics, Inc.* v. *Pulse Electronics, Inc.*, 136 S. Ct. 1923, 1928 (2016); *Limelight Networks, Inc.* v. *Akamai Technologies, Inc.*, 134 S. Ct. 2111, 2120 (2014). It should do so again here.

The Federal Circuit's purported reservation of the question whether undisclosed commercial sales would foreclose patentability under the AIA, App., *infra*, 43a, provides no basis for deferring review. For starters, Judge O'Malley, who was a member of the original panel, understood the panel's decision unequivocally to hold that the AIA "did not change" the on-sale bar, which had previously been construed to reach undisclosed sales. See *id.* at 3a-4a. The panel itself suggested that its holding would extend to undisclosed sales, on the ground that the AIA's sponsors failed to cite by name (and therefore abrogate) pre-AIA cases applying the on-sale bar. See p. 12, *supra*.

But even on its own terms, the Federal Circuit swept broadly, holding that, "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." *Id.* at 43a. That holding applies to all commercial sales that are publicly disclosed—for example, in securities filings.

Moreover, no party or amicus argued below that the disclosure of the *fact* of a sale is legally relevant. See p. 11, *supra*. The distinction between "disclosed secret sales" and "undisclosed secret sales" was an invention of the Federal Circuit, and, for all the reasons discussed above, it has no basis in the text of the statute. This Court should not reward the Federal Circuit's attempt to shield its decision from further review by portraying it as narrow.

For the same reasons, Judge O'Malley's revisionist effort to characterize the panel's decision as fact-bound is unavailing. The facts recited by Judge O'Malley in her concurring opinion at the rehearing stage informed the Federal Circuit's determination whether petitioner's agreements qualified as a commercial sale under its precedents applying the pre-AIA on-sale bar (most notably, *Medicines Co.* v. *Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) (en banc)). Compare App., *infra*, 27a-34a, with *id.* at 4a-7a (O'Malley, J., concurring in the denial of rehearing). But they have nothing to do with the Federal Circuit's *legal* conclusion that, after the AIA, the disclosure of the existence of a commercial sale invalidates a patent.

For purposes of this petition, this Court may assume that the Federal Circuit correctly determined that the MGI agreements satisfy the pre-AIA on-sale bar; it is the Federal Circuit's core holding about the effect of the AIA that demands this Court's review. That holding has created tremendous uncertainty regarding the scope of the AIA's on-sale bar. A grant of certiorari in this case is nec-

essary to resolve that uncertainty and to correct the Federal Circuit's profoundly flawed and outmoded approach to statutory interpretation.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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FEBRUARY 2018

APPENDIX

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APPENDIX A

NOTE: This order is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

HELSINN HEALTHCARE S.A.,
Plaintiff-Appellee

v.

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Defendants-Appellants

2016-1284, 2016-1787

Appeals from the United States District Court for the District of New Jersey in Nos. 3:11-cv-03962-MLC-DEA, 3:11-cv-05579-MLC-DEA, 3:13-cv-05815-MLC-DEA, Judge Mary L. Cooper

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ON PETITION FOR REHEARING EN BANC

Before PROST, *Chief Judge*, NEWMAN, MAYER*, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, and HUGHES, *Circuit Judges*.** O'MALLEY, *Circuit Judge*, concurring in the denial of panel rehearing.

PER CURIAM.

ORDER

Appellee Helsinn Healthcare S.A. filed a petition for rehearing en banc. A response to the petition was invided by the court and filed by appellants Teva Pharmaceuticals USA, Inc. and Teva Pharmeceutical Industries, Ltd. The petition was first referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circutit judges who are in regular active service.

Upon consideration therof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on January 23, 2018.

FOR THE COURT

January 16, 2018
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

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* Circuit Judge Mayer participated only in the decision on the petition for panel rehearing.

** Circuit Judge Stoll did not participate.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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Plaintiff-Appellee

v.,

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
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O'MALLEY, *Circuit Judge*, concurring in the denial of panel rehearing.

Helsinn Healthcare S.A. ("Helsinn") petitions the court for rehearing, arguing that the America Invents Act ("AIA") changed the meaning of the on-sale bar under 35 U.S.C. § 102 so as to disturb settled law. Helsinn contends that, under the new standard established by the AIA, the Supply and Purchase Agreement ("Agreement") between Helsinn and MGI Pharma, Inc. ("MGI") does not trigger application of the on-sale bar with respect to U.S. Patent No. 8,598,219. Because I believe the panel decision correctly concluded that the AIA did not

change longstanding precedent governing the on-sale bar, and that the Agreement triggers the on-sale bar under that precedent, I agree that panel rehearing is not warranted and therefore concur in the denial of Helsinn's petition.

I write separately because I believe Helsinn's petition and various amici briefs filed in support thereof mischaracterize certain aspects of our panel opinion and advance policy-based criticisms about aspects of the law that this court is not at liberty to change. I believe those points merit response.

I.

I begin with the mischaracterizations. There are three: (1) we concluded that every time the fact of a sale is disclosed to the public, regardless of the nature of the disclosure, the on-sale bar in 35 U.S.C. § 102 will be triggered; (2) our decision implies that all supply-side agreements with third-party distributors will constitute invalidating transactions; and (3) our holding is inconsistent with our *en banc* decision in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016).

First, Helsinn and some amici believe the panel decision concluded that all public sales will trigger the on-sale bar. To support that contention, they place undue weight on a single sentence in the decision that states, "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017).

This sentence does not suggest that publicly announced agreements will always trigger the on-sale bar,

nor does it suggest that secret sales never will. As we explained in *Medicines*, the confidential nature of a transaction is just one of several factors for determining whether the transaction rises to the level of a commercial sale such that the on-sale bar would apply. 827 F.3d at 1376 ("Like the absence of title transfer, the confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature."); *Helsinn*, 855 F.3d at 1364 (explaining that, in *Medicines*, "[w]e noted that the absence of the passage of title, the confidential nature of a transaction, and the absence of commercial marketing of the invention all counsel against applying the on-sale bar"). That single factor, however, is not dispositive of the analysis. Indeed, other factors may counsel in favor of finding that a publicly announced transaction is insufficient to trigger the on-sale bar, depending on the circumstances. *See, e.g.*, *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1050 (Fed. Cir. 2001) (holding that promotional activity was insufficient to trigger the on-sale bar).

All that our panel opinion held was that the *particular* agreement at issue triggered the on-sale bar, in part—but not exclusively—because it was made public. Helsinn did not just disclose the fact that it had entered into a supply agreement with MGI; a partially-redacted copy of the Agreement itself was included with MGI's Form 8-K filing. *Helsinn*, 855 F.3d at 1361. As the panel noted, the Agreement described the claimed drug formulation "in detail." *Id.* at 1366. The Agreement also "expressly contemplated" the passage of title, and made clear that Helsinn "commercially marketed its invention before the critical date." *Id.* at 1364. All of these factors weighed

strongly in favor of finding that the on-sale bar was triggered. *Id.* at 1364–65, 1371.[1]

Second, we did not hold that all supply-side arrangements for future sales will invalidate a later-filed patent. In fact, we expressly held otherwise. *See id.* at 1371 ("We do not find that distribution agreements will always be invalidating under § 102. We simply find that this particular Supply and Purchase Agreement is."); *see also Medicines*, 827 F.3d at 1381 ("We hold . . . that a contract manufacturer's sale to the inventor of manufacturing services where neither title to the embodiments nor the right to market the same passes to the supplier does not constitute an invalidating sale under § 102(b)."). As we explained in *Medicines*, inquiries under § 102's on-sale bar provision are fact-intensive and require the application of a variety of commercial law principles to the allegedly triggering transaction at issue. *See Medicines*, 827 F.3d at 1375–76. While it may be difficult to structure such transactions to avoid the tests set forth in *Medicines* and

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[1] Some amici assert that Congress intended to abrogate the standard governing secret sales set forth in *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), and urge us to use this case as a vehicle to acknowledge that fact. *See, e.g.*, Amicus Br. of Naples Roundtable, Inc. 12–16. Because the Supreme Court seems to have endorsed the general principles articulated in *Metallizing*, *see Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998) (quoting *Metallizing* for the proposition that an inventor "shall not exploit his discovery competitively after it is ready for patenting"), it is questionable whether we could depart from them now. As we stated in our panel opinion, moreover, the rule in *Metallizing* simply is not implicated by the facts of this case; the Agreement was not a "secret sale." *See Helsinn*, 855 F.3d at 1368–69 (declining "the invitation by the parties to decide th[e] case more broadly than necessary").

applied in *Helsinn*, nothing we said in the panel decision would make it impossible to do.

Third, Helsinn and its amici contend that, because we recognized in *Medicines* that our holding there would avoid disadvantaging small companies who do not otherwise have the resources to manufacture products in-house, it is inconsistent for us not to strive to protect those same companies with respect to their distribution needs. That we refused to find in *Medicines* that the mere stockpiling of a patented invention constitutes an invalidating activity does not lead to the conclusion that distribution agreements, regardless of their commercial character, are also not invalidating. We held in *Medicines* that, where a transaction does not bear the hallmarks of a commercial sale—even where the transaction results in stockpiling of product for future potential sales—the on-sale bar will not be triggered. *See id.* at 1377–79. In other words, we declined to base our decision about the application of the on-sale bar on a policy desire to avoid stockpiling. Where, as here, however, the tests laid out in *Medicines* lead to the conclusion that a transaction carries all indicia of a commercial sale, we cannot shield the transaction from the reach of § 102 merely because that conclusion would make it more difficult for certain companies to establish a distribution chain for those same products. The fact that we did not allow the policy implications of our decision in *Helsinn* to overcome our analysis of the commercial nature of the Agreement is entirely *consistent* with *Medicines*. Congress may decide that certain commercial sales or offers for sale should be exempted from the reach of § 102 for policy reasons; we may not do so, however.

II.

I turn now to the criticisms of our conclusion that the AIA had no impact on the application of the on-sale bar to these facts.

While Helsinn and its supporting amici say much about why they think the law relating to the on-sale bar should be narrower than it traditionally has been, and point to the statements of a few legislators who expressed similar views, they make few legal arguments to support the conclusion that Congress actually changed that aspect of patent law.

Helsinn's only argument directed to the text of the statute is that the new phrase "or otherwise available to the public" appearing in post-AIA § 102(a) modifies the preceding phrase "on sale," and therefore alters the traditional concept of what constitutes a "sale" for purposes of the on-sale bar. Helsinn argues that we should apply the "series-modifier" doctrine, which dictates that, "[w]hen a modifier is set off from a series of antecedents by a comma, the modifier should be read to apply to each of those antecedents." *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008) (internal quotation marks omitted). According to Helsinn, "otherwise available to the public" restricts every preceding phrase in § 102(a), including the phrase "on sale," to activities that make the claimed invention fully available to "the public."

There are several problems with Helsinn's argument, however. First, the use of the series-modifier doctrine only applies in limited circumstances not present here.[2]

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[2] The series-modifier rule is applicable only when "several words are followed by a clause which is applicable as much to the

Second, the Supreme Court has explained that terminal limiting clauses or phrases ordinarily should be read to modify only the noun or phrase that immediately precedes them—known as the "last antecedent" doctrine. *See Barnhart v. Thomas*, 540 U.S. 20, 26 (2003). This is especially true where, as here, the phrase at issue is separated from the preceding phrases with a comma, followed by use of the word "or," implying that what follows the comma is something different from and independent of the preceding concepts. This doctrine implies that "to the public" limits only "otherwise available." In other words, "otherwise available to the public" is a catch-all provision that encompasses means by which the claimed invention can be disclosed to the pub[illegible] that are not otherwise accounted for in § 102(a).

Helsinn's grammatical argument also must compete with numerous other legal arguments that support a contrary conclusion—i.e., that Congress meant to leave the on-sale bar intact:

- Congress chose not to modify the term "on sale," as it had previously appeared in § 102(b), suggesting that Congress intended for that

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first and other words as to the last." *Paroline v. United States*, 134 S. Ct. 1710, 1721 (2014) (quoting *Porto Rico Ry., Light & Power Co. v. Mor*, 253 U.S. 345, 348 (1920)); *see also Lockhart v. United States*, 136 S. Ct. 958, 963 (2016) (explaining that the doctrine is most appropriate when it would not "take[ ] more than a little mental energy to process the individual entries in the list" so as to "carry the modifier across them all"). Here, "otherwise available to the public" is not equally applicable to all preceding phrases because each phrase—i.e., "patented," "printed publication," and "public use"—recites a disclosure that is necessarily public. Helsinn's reading of the statute would therefore create redundancies within § 102(a) itself.

term to take on the meaning that courts had attributed to it for well over a century. "[I]t is a cardinal rule of statutory construction that, when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken." *FAA v. Cooper*, 566 U.S. 284, 292 (2012) (internal quotation marks omitted); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) ("When all (or nearly all) of the relevant judicial decisions have given a term or concept a consistent judicial gloss, we presume Congress intended the term or concept to have that meaning when it incorporated it into a later-enacted statute." (internal quotations marks omitted)).[3]

- Helsinn's reading of post-AIA § 102(a) renders the "on sale" provision superfluous because that reading would equate "on sale" with "public use," which is already provided for in the statute. Such a reading is disfavored. *See Hibbs v. Winn*, 542 U.S. 88, 101 (2004) ("A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous." (internal quotation marks omitted)).

- Post-AIA § 102(b)(1) provides a grace period where (in paragraph (A)) a "disclosure" is made

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[3] Notably, post-AIA § 102 recites *all* of the key terms that appeared in pre-AIA § 102—i.e., "patented," "described in a printed publication," "in public use," and "on sale"—verbatim, and in the same order.

> by the inventor, or (in paragraph (B)) the subject matter disclosed by a third party had, before such disclosure, been "publicly disclosed" by the inventor. If all prior art events—i.e., all "disclosures"—recited in § 102(a) were already public disclosures, the word "publicly" in § 102(b)(1)(B) would be redundant, and there would be no need for a separate rule for third-party disclosures. This suggests that not all prior art events in § 102(a) are public events. *See United States v. Alaska*, 521 U.S. 1, 59 (1997) ("The Court will avoid an interpretation of a statute that 'renders some words altogether redundant.'" (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 574 (1995)).

As the panel opinion noted, "[i]f Congress intended to work such a sweeping change to our on-sale bar jurisprudence . . . , it would [have done] so by clear language." *Helsinn*, 855 F.3d at 1371 (quoting *Dir., OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 321 (1983)). It would not have done so in a manner that is at odds with so many principles of statutory interpretation.

Helsinn's legislative history arguments do not fare much better. As we stated in the panel opinion in this case, the legislative statements to which Helsinn cites are at best equivocal. *See id.* at 1368–71.[4] And numerous other

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[4] It is a stretch to characterize floor statements by individual Senators made the day after the bill was passed as legislative "history." If anything is reflective of what Congress intended, beyond the words used in the enacted statute, it would seem that the House Report accompanying the 2007 bill—which reintroduced the "public use" and

aspects of the legislative history indicate both that Congress's primary focus when amending § 102 was on the nature and content of prior art printed publications, not on the on-sale bar, and that Congress several times considered, but rejected, the very changes to the on-sale bar Helsinn urges us to conclude were actually made. *Compare* S. Rep. No. 111-18, at 60 (2009) (Senator Kyl and others urging the Senate to remove from the precursor bill "patent-forfeiture provisions that apply only to non-public prior art"), *with* Comm. on the Judiciary, Markup of H.R. 1249, at 101 (Apr. 14, 2011) (Representative Lofgren offering an amendment to prevent the elimination of "public use" and "on sale" from the definition of prior art, citing "strenuous concerns" about "the deletion of specific categories of prior art with well established meanings"); *see also* Br. Opp'n Reh'g En Banc at 10–12 (describing evolution of bill); *Hamdan v. Rumsfeld*, 548 U.S. 557, 579–80 (2006) ("Congress' rejection of the very language that would have achieved the result the Government urges here weighs heavily against the Government's interpretation.").

III.

That leaves us with the policy-based criticisms of the panel opinion. Helsinn and amici criticize the panel decision for failing to properly consider what they characterize as the key policy underlying the on-sale bar—the "policy against removing inventions from the public domain which the public justifiably comes to believe are freely

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"on sale" language—would be. That report confirms that the Committee used "the current § 102(b) as the template from which to define the scope of prior art in the Act, primarily because of how the terms 'in public use' and 'on sale' have been interpreted by the courts." H.R. Rep. No. 110-314, at 57 (2007).

available due to commercialization." *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985). They argue that a sale between an inventor and a supplier does not place the invention in the public domain in the first place, and that allowing a patent on the invention after such a sale therefore does not remove the invention from the public domain. Because this is true, they assert, the on-sale bar should not be triggered by distribution agreements.

As an initial matter, this policy goal is not the only one that animates the on-sale bar. Both the Supreme Court and this court have recognized that another concern underlying the on-sale bar—and in fact, the "overriding" concern—is the risk that an inventor will commercially exploit his invention beyond the statutory term. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998) (noting that § 102 "serves as a limiting provision" insofar as it "confin[es] the duration of the [patent] monopoly to the statutory term"); *STX, LLC v. Brine, Inc.*, 211 F.3d 588, 590 (Fed. Cir. 2000) ("The overriding concern of the on-sale bar is an inventor's attempt to commercialize his invention beyond the statutory term."); *cf. Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1858) ("[T]he inventor who designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public, comes not within the policy or objects of the Constitution or acts of Congress.").

We have described other policy goals as well, including promoting the early filing of patent applications, for example. *See Medicines*, 827 F.3d at 1372; *see also Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829) (noting that allowing an inventor to "hold back from the knowledge of the public the secrets of his invention" and thereafter file

for a patent application "would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries"). These policy concerns do not always align and may at times lead to a conclusion that is contrary to the conclusion reached by considering *only* whether a sale injects the invention into the public domain.

Whatever the various policy goals behind the on-sale bar might be, the Supreme Court's rigid two-part test articulated in *Pfaff v. Wells Electronics, Inc.*, prevents us from expressly considering and balancing such goals. Prior to *Pfaff*, we applied a "totality of the circumstances" test that took into account the policy goals underlying the on-sale bar. *See, e.g.*, *Evans Cooling Sys., Inc. v. Gen. Motors Corp.*, 125 F.3d 1448, 1451 (Fed. Cir. 1997) ("[T]he totality of the circumstances and the policies underlying the bar must be considered in determining whether a definite offer for sale triggering section 102(b) has been made."), *abrogated by Pfaff*, 525 U.S. 55; *Ferag AG v. Quipp Inc.*, 45 F.3d 1562, 1566 (Fed. Cir. 1995) ("The underlying policies are what drives the section 102(b) analysis."), *abrogated by Pfaff*, 525 U.S. 55; *Medicines*, 827 F.3d at 1372. In rejecting that test, the *Pfaff* Court made clear "that we are not to look to broad policy rationales in assessing whether the on-sale bar applies." *Medicines*, 827 F.3d at 1377; *Pfaff*, 525 U.S. at 65–67 & n.11. Instead, "we are to apply a straightforward two-step process—one which permits an inventor to 'both understand and control the first commercial marketing of his invention.'" *Medicines*, 827 F.3d at 1377 (quoting *Pfaff*, 525 U.S. at 67). And, in doing so, we are to focus on the commercial nature of the transaction at issue. The now-governing test therefore leaves little room for policy-based inquiries. Unless and until the Supreme Court articulates a more flexible test

that allows courts to expressly consider the policies that animate the on-sale bar, and to give priority to one of those goals over others, our on-sale bar jurisprudence will not necessarily promote any given policy goal.

It is fair to question whether such distribution agreements *should* fall within the scope of the on-sale bar in light of the policy goals discussed above. Parties enter into distribution agreements for the purpose of making preparations to sell products to the public in the *future*, but these agreements do not themselves effectuate consummated sales to end users. And there is often a need to make distribution agreements public to induce investors to supply funding for product development. But when the activity shifts from pre-commercial to commercial activity, the § 102 calculus shifts as well.

We also must remember that "on sale" in § 102 covers not only consummated sales, but mere offers for sale as well.[5] Thus, an offer for sale between a supplier and dis-

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[5] Our "offer for sale" law is well established, and the Supreme Court has confirmed that "on sale" encompasses mere offers to sell. *See Pfaff*, 525 U.S. at 67 (stating the on-sale bar applies if, among other things, "the product [is] the subject of a commercial offer for sale"); *Helsinn*, 855 F.3d at 1370–71; *see also D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1150 (Fed. Cir. 1983) ("That no sale was actually made to International Crest is irrelevant. An offer to sell is sufficient under the policy animating the statute, which proscribes not a sale, but a placing 'on sale.'"); *Dittgen v. Racine Paper Goods Co.*, 181 F. 394, 398 (E.D. Wis. 1910) ("[A] device will be on sale within the meaning of the law, if it is offered for sale, whether any specimen of it is actually sold or not." (internal quotation marks omitted)); *Covert v. Covert*, 106 F. 183, 188 (W.D.N.Y. 1901) ("The offer to sell the wagon jack more than two years before filing application is enough. Actual sale is not necessary."), *aff'd*, 115 F. 493 (2d Cir. 1902).

tributor can trigger the on-sale bar even though the transaction is several steps removed from the consuming public actually acquiring the invention. It is difficult to see how Helsinn's theory of § 102, and its belief that the invention must be made available to the public before the on-sale bar is triggered, squares with years of case law regarding the invalidating nature of mere offers for sale. Congress or the Supreme Court could redefine "on sale" to exclude mere offers for sale; again, we cannot.

The on-sale bar's applicability to commercial agreements entered into for the purpose of preparing to make future sales has provoked criticism long before Helsinn. *Cf. McCreery Eng'g Co. v. Mass. Fan Co.*, 195 F. 498, 502 (1st Cir. 1912) (noting that "there is reason to doubt whether an offer to deliver an article at a future time is in substance a putting on sale before the time of actual delivery"). Until Congress amends § 102 to exclude such agreements from its scope, or the Supreme Court changes the analysis we are to employ when considering such transactions, these criticisms will continue.

For these reasons, I concur in the denial of panel rehearing.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

HELSINN HEALTHCARE S.A.,
Plaintiff-Appellee

v.

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Defendants-Appellants

2016-1284, 2016-1787

Appeals from the United States District Court for the District of New Jersey in Nos. 3:11-cv-03962-MLC-DEA, 3:11-cv-05579-MLC-DEA, 3:13-cv-05815-MLC-DEA, Judge Mary L. Cooper

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Decided: May 1, 2017

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Research and Manufacturers of America, Biotechnology Innovation Organization. Also represented by ROBERT MANHAS, THOMAS SAUNDERS.

Before DYK, MAYER, AND O'MALLEY, Circuit Judges.

DYK, Circuit Judge.

Helsinn Healthcare S.A. ("Helsinn") is the owner of the four patents-in-suit directed to intravenous formulations of palonosetron for reducing or reducing the likelihood of chemotherapy-induced nausea and vomiting ("CINV").

Helsinn brought suit against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva") alleging that the filing of Teva's Abbreviated New Drug Application ("ANDA") constituted an infringement of various claims of those patents. Teva defended, *inter alia*, on the ground that the asserted claims were invalid under the on-sale bar provision of 35 U.S.C. § 102. The district court found that the patents-in-suit were not invalid. With respect to three of the patents, which are governed by the pre-Leahy-Smith America Invents Act ("pre-AIA") version of § 102, the district court concluded that there was a commercial offer for sale before the critical date, but that the invention was not ready for patenting before the critical date. With respect to the fourth patent, which is governed by the AIA version of § 102, Pub. L. No. 112-29, § 3(b), 125 Stat. 284, 285–86 (2011), the district court concluded that there was no commercial offer for sale because the AIA changed the relevant standard and that, in any event, the invention was not ready for patenting before the critical date.

We reverse. The asserted claims of the patents-in-suit were subject to an invalidating contract for sale prior to the critical date of January 30, 2002, and the AIA did not change the statutory meaning of "on sale" in the circumstances involved here. The asserted claims were also ready for patenting prior to the critical date.

BACKGROUND

Helsinn owns four patents, U.S. Patent Nos. 7,947,724 ("'724 patent"), 7,947,725 ("'725 patent"), 7,960,424 ("'424 patent"), and 8,598,219 ("'219 patent") (collectively, "the patents-in-suit"), directed to reducing the likelihood of CINV. CINV is a serious side effect of chemotherapy treatment.

The use of palonosetron to treat CINV was not new. Indeed, U.S. Patent No. 5,202,333 ("'333 patent") taught that an intravenous formulation of palonosetron is "useful in the prevention and treatment of emesis," '333 patent, col. 9 ll. 56–57, including "emesis induced by . . . treatment for cancer with . . . chemotherapy," *id.* col. 10 ll. 7–9. The '333 patent is now expired. The patents-in-suit purport to disclose novel intravenous formulations using unexpectedly low concentrations of palonosetron that were not taught by the prior art. All four of the patents-in-suit claim priority to a provisional patent application filed on January 30, 2003. The critical date for the on-sale bar is one year earlier, January 30, 2002. The significance of the critical date is that a sale of the invention before that date can be invalidating.[1]

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[1] The parties agree that the '219 patent has the same critical date as the pre-AIA patents for the on-sale bar even though it is governed

Helsinn alleged infringement of claims 2 and 9 of the '724 patent, claim 2 of the '725 patent, claim 6 of the '424 patent, and claims 1, 2, and 6 of the '219 patent (collectively, "the asserted claims"). Claim 2 of the '725 patent is representative of the asserted claims of the '724, '725, and '424 patents.

> 2. A pharmaceutically stable solution for reducing emesis or reducing the likelihood of emesis comprising:
>
> a) 0.05 mg/mL palonosetron hydrochloride, based on the weight of the free base, in a sterile injectable aqueous carrier at a pH of from 4.5 to 5.5;
>
> b) from 0.005 mg/mL to 1.0 mg/mL EDTA; and
>
> c) mannitol in an amount sufficient to tonicify said solution, in a concentration of from about 10 mg/ml to about 80 mg/ml

'725 patent, col. 10 ll. 11–19.

Claim 1 is representative of the asserted claims of the '219 patent.

> 1. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:
>
> palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

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by the AIA. The one-year grace period in the AIA is less protective than under pre-AIA § 102(b) for reasons not relevant here.

> from 0.005 mg/mL to 1.0 mg/mL EDTA; and
>
> from 10 mg/mL to about 80 mg/mL mannitol,
>
> wherein said formulation is stable at 24 months when stored at room temperature.

'219 patent, col. 10 ll. 2–12. The claims of the patents-in-suit to some extent all express the same concepts in different terms. For instance, the '724, '725, and '424 patents claim a 0.05 mg/ml concentration of palonosetron, which equates to a total dose of 0.25 mg when administered in a 5 ml solution. The '219 patent expressly claims a fixed dose of 0.25 mg of palonosetron in a 5 ml solution. It is undisputed that each asserted claim covers the 0.25 mg dose of palonosetron. In order to simplify the relevant discussion, we refer to the patents as covering the 0.25 mg dose.

In 1998, Helsinn acquired a license under the '333 patent from Roche Palo Alto LLC ("Roche") to palonosetron and all intellectual property resulting from ongoing palonosetron research. Roche and its predecessor, Syntex (U.S.A.) Inc. ("Syntex"), had already conducted Phase I and Phase II clinical trials. A Phase II trial—Study 2330—found that the 0.25 mg dose "was effective in suppressing chemotherapy-induced emesis for 24 hours." J.A. 32, 1636. Helsinn then submitted safety and efficacy protocols for Phase III clinical trials to FDA in early 2000, proposing to study two dosages—0.25 mg and 0.75 mg. By early 2001 the Phase III trials were ongoing but not yet completed.

On April 6, 2001, almost two years before applying for a patent, Helsinn and MGI Pharma, Inc. ("MGI"), an oncology-focused pharmaceutical company that markets

and distributes in the United States, entered into two agreements: (1) a License Agreement and (2) a Supply and Purchase Agreement. These agreements were announced in a joint press release of the two corporations and in MGI's Form 8-K filing with the Securities and Exchange Commission ("SEC"), which included partially-redacted copies of both agreements. *See* MGI Pharma Inc., Current Report (Form 8-K) Ex. 99.1 (Apr. 25, 2001) [hereinafter License Agreement]; MGI Pharma Inc., Current Report (Form 8-K) Ex. 99.2 (Apr. 25, 2001) [hereinafter Supply and Purchase Agreement].

Under the terms of the License Agreement, MGI agreed to pay $11 million in initial payments to Helsinn, plus additional future royalties on distribution of "products" in the United States. The parties agree that the "products" covered by the License Agreement were 0.25 mg and 0.75 mg doses of palonosetron.

Under the Supply and Purchase Agreement, MGI agreed to purchase exclusively from Helsinn, and Helsinn agreed to supply MGI's requirements of the 0.25 mg and 0.75 mg palonosetron products, or whichever of the two dosages were approved for sale by FDA. The agreement required MGI to submit purchase forecasts to Helsinn and to place firm orders at least 90 days before delivery. It also specified that such orders would be "subject to written acceptance and confirmation by [Helsinn] before becoming binding." Supply and Purchase Agreement, *supra*, art. 4.2. But, in the event that Helsinn were unable to meet MGI's firm orders and to the extent they fell within the previously forecasted amount, Helsinn would then be obligated to designate a third party manufacturer to supply MGI with the product. The agreement specified price (29% of the gross sales price by MGI with a minimum of

$28.50 per vial), method of payment (wire transfer within 30 days of receipt of an invoice), and method of delivery (DDU—which means delivery duty unpaid). *See* Black's Law Dictionary 481, 521 (10th ed. 2014) (defining "DDU" and "delivery duty unpaid").

The License Agreement made reference to the ongoing clinical trials and stated that in the event that the results were unfavorable and FDA did not approve the sale of either dosage of the product, Helsinn could terminate the agreement. If the License Agreement were terminated, the Supply and Purchase Agreement would "terminate automatically." Supply and Purchase Agreement, *supra*, art. 11.1.

All of the above information about the transaction was publicly disclosed with two exceptions. The two features of the agreements that were not publicly disclosed were the price terms and the specific dosage formulations covered by the agreements—that is the 0.25 and 0.75 mg doses.

Helsinn admitted at oral argument that the agreement was binding as of its effective date, April 6, 2001, and that it would cover either or both of the 0.25 and 0.75 mg doses, subject to FDA approval. Helsinn also agreed that, if the Phase III trials were successful and the products were approved by FDA, then the agreement obligated MGI to purchase and Helsinn to supply the approved doses. But if FDA did not approve either dose, then the agreement likewise would terminate automatically with the License Agreement. As Helsinn stated, in such a scenario "both

parties [could] accept that fact and walk away."[2] Oral Arg. at 36:37–40, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2016-1284.mp3.

After the signing of the agreements, and still before the critical date, Helsinn prepared preliminary statistical analysis of the earliest Phase III trial on January 7, 2002. The data showed that 81% of patients who received the 0.25 mg dose of palonosetron experienced relief from CINV for 24 hours. After the critical date of January 30, 2002, Helsinn submitted its preliminary Phase III data to FDA in early February. In September 2002, after the successful completion of all Phase III trials, Helsinn filed its New Drug Application for the 0.25 mg dose, but did not seek FDA approval of the 0.75 mg dose. On January 30, 2003, Helsinn filed a provisional patent application covering the 0.25 mg dose (and also the 0.75 mg dose). FDA issued approval for the 0.25 dose on July 2003. From 2005 to 2006, Helsinn filed three patent applications and these issued as the '724, '725, and '424 patents. In May 2013, after the effective date of the AIA, Helsinn filed a fourth patent application which issued as the '219 patent. All four patents cover the 0.25 mg dose, are listed in FDA's "Orange Book," and claim priority to the January 30, 2003 date of the provisional application.

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[2] Even if FDA approval were not an express condition of a contract for sale of a pharmaceutical, there would be a strong argument for implying such a condition since federal law prohibits the introduction of new drugs into interstate commerce without FDA approval. *See* 21 U.S.C. § 355.

In 2011, Teva filed an ANDA seeking FDA approval to market a generic 0.25 mg palonosetron product.[3] Teva's ANDA filing included a Paragraph IV certification that the claims of the patents-in-suit were invalid and/or not infringed. Helsinn then brought suit under the Hatch–Waxman Act, 35 U.S.C. § 271(e)(2)(A), alleging infringement of the patents-in-suit by the ANDA filing.

The district court held a bench trial. The district court held that Teva's 0.25 mg dose infringed all of the patents-in-suit. In addressing the on-sale issue, the court applied the two-step framework of *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), which requires that there was a sale or offer for sale and that the claimed invention was ready for patenting for the on-sale bar under 35 U.S.C. § 102 to apply. As to the '724, '725, and '424 patents, the court found that pre-AIA law applied under § 102(b) and that the MGI Supply and Purchase Agreement was a contract for a future sale of a commercial product embodying the 0.25 mg dose and therefore constituted a sale under § 102(b). But, the court found that the claimed invention was not reduced to practice before the critical date of January 30, 2002, and therefore was not ready for patenting under the second prong of *Pfaff*. The district court did not address

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[3] We treat this case as involving only the 0.25 mg dose of palonosetron. Teva also filed an ANDA for a 0.075 mg dose of palonosetron in 1.5 ml of solution. It is undisputed that this product has a concentration of 0.05 mg/ml and falls within the asserted claims of the '724, '725, and '424 patents. There is no contention that the 0.075 mg dose was on sale before the critical date or that the Supply and Purchase Agreement covered the 0.075 mg dose. But the parties agree that the same claims cover both the 0.25 mg dose and the 0.075 mg dose, and the case stands or falls on whether the asserted claims covering the 0.25 mg dose are invalid under the on-sale bar. In other words, if the claims covering the 0.25 mg dose are invalid, there are not valid and asserted claims covering the 0.075 mg dose.

whether the invention was ready for patenting on the alternative theory that Teva had shown that the inventor had created enabling descriptions before the critical date. *See Pfaff*, 525 U.S. at 67–68.

As to the '219 patent governed by the AIA, the court held that the AIA changed the meaning of the on-sale bar and § 102(a)(1) now "requires a *public* sale or offer for sale of the claimed invention." J.A. 113 (emphasis added). The court concluded that, to be "public" under the AIA, a sale must publicly disclose the details of the invention. The court found that the MGI Supply and Purchase Agreement did not constitute a public sale or commercial offer for sale because, although it disclosed the sale agreement and substance of the transaction, it failed to publicly disclose the 0.25 mg dose. The '219 patent also was not ready for patenting before the critical date. Therefore, the district court found that the asserted claims of the four patents were not invalid.

Teva appeals. We have jurisdiction under 28 U.S.C. § 1295(a).

DISCUSSION

Application of the on-sale bar under 35 U.S.C. § 102 is ultimately a question of law that we review de novo. *Robotic Vision Sys., Inc. v. View Eng'g, Inc.*, 249 F.3d 1307, 1310 (Fed. Cir. 2001). The factual findings underlying the district court's conclusion are reviewed for clear error. *Id.* Under *Pfaff*, application of the on-sale bar requires that (1) "the product must be the subject of a commercial offer for sale" and (2) "the invention must be ready for patenting." 525 U.S. at 67.

I

We first address whether the invention of the '724, '725, and '424 patents was subject to a sale or offer for sale prior to the critical date. We recently had occasion to address the pre-AIA on-sale bar en banc in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016). There we established a framework for determining whether there is an offer for sale. We explained that the question must be "analyzed under the law of contracts as generally understood" and "must focus on those activities that would be understood to be commercial sales and offers for sale 'in the commercial community.'" *Id.* at 1373 (quoting *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001)). While acknowledging that it is not of "talismanic significance" to our inquiry, "[a]s a general proposition, we will look to the Uniform Commercial Code ('UCC') to define whether ... a communication or series of communications rises to the level of a commercial offer for sale." 827 F.3d at 1373 (alteration in original) (quoting *Grp. One*, 254 F.3d at 1047). A sale occurs when there is a "contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold." *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1361 (Fed. Cir. 2010) (internal quotation marks omitted).

In *Medicines* we also pointed to other factors that are important to this analysis, but noted that, like the UCC itself, none is determinative individually. We noted that the absence of the passage of title, the confidential nature of a transaction, and the absence of commercial marketing of the invention all counsel against applying the on-sale bar. *Id.* at 1375–76. We deemed these factors important because they helped shed light on whether a transaction would be understood "in the commercial community" to constitute a commercial offer for sale. *Id.* at 1373 (quoting

Grp. One, 254 F.3d at 1047). But those additional factors are not at issue in this case. There is no suggestion that the Supply and Purchase Agreement did not involve transfer of title; it expressly contemplated it. And, while certain details were redacted from the publicly disclosed copy of the Supply and Purchase Agreement, Helsinn does not argue that the *transaction* itself between Helsinn and MGI remained confidential. Helsinn also commercially marketed its invention before the critical date. It publicly sought "marketing partners for its patented [palonosetron] product," J.A. 63–64 n.26, and ultimately contracted with MGI "to distribute, promote, market, and sell" the claimed invention, J.A. 2255.

We agree with the district court that there was a sale for purposes of pre-AIA § 102(b) prior to the critical date because there was a sale of the invention under the law of contracts as generally understood.

Helsinn admits that the Supply and Purchase Agreement was binding as of its effective date, April 6, 2001, and that, if FDA approved the 0.25 mg dose and/or the 0.75 mg dose of palonosetron, the agreement obligated Helsinn to sell and MGI to purchase those products. The Supply and Purchase Agreement bears all the hallmarks of a commercial contract for sale.[4] It obligated MGI to purchase exclusively from Helsinn and obligated Helsinn to

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[4] *See, e.g.*, *Merck & Cie* v. *Watson Labs., Inc.*, 822 F.3d 1347, 1351 (Fed. Cir. 2016) (offer "provid[ed] essential price, delivery, and payment terms"); *Cargill, Inc.* v. *Canbra Foods, Ltd.*, 476 F.3d 1359, 1369 (Fed. Cir. 2007) (offer "explicitly set[ ] forth an amount . . . to be delivered to P & G, at a specified unit price, and under a standard contract designation, FOB (free on board)"); *Linear Tech. Corp.* v. *Micrel, Inc.*, 275 F.3d 1040, 1052 (Fed. Cir. 2001) (offers "included quantity terms and clearly identified the requested product").

supply MGI's requirements of the 0.25 and 0.75 mg doses if approved by FDA.

The agreement here included other specific terms, such as price, method of payment, and method of delivery. Even though MGI's firm orders pursuant to the agreement were ostensibly "subject to written acceptance and confirmation by [Helsinn] before becoming binding," J.A. 2260, Helsinn was nonetheless obligated to meet or designate a third party manufacturer to meet MGI's firm orders. The public 8-K filing described the Supply and Purchase Agreement as obligating Helsinn to supply MGI's "requirements of finished product." MGI Pharma Inc., Current Report (Form 8-K), at 2 (Apr. 25, 2001). Under our decision in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 424 F.3d 1276 (Fed. Cir. 2005), the fact that an agreement covered one party's requirements as opposed to a specified quantity does not prevent application of the on-sale bar. *Id.* at 1281–82.

Despite these facts, Helsinn argues that the Supply and Purchase Agreement is not invalidating because at the critical date it was uncertain whether FDA would approve the 0.25 mg dose, and FDA approval was a condition precedent to the sale.

There can be no real dispute that an agreement contracting for the sale of the claimed invention contingent on regulatory approval is still a commercial sale as the commercial community would understand that term. The UCC expressly provides that a "purported present sale of future goods ... operates as a contract to sell." UCC § 2–105(2) (defining "future goods" as "[g]oods which are not both existing and identified"). This is true irrespective of whether those future goods have yet to receive necessary regulatory approval. A contract for sale that includes a

condition precedent is a valid and enforceable contract. *See BG Grp., PLC v. Republic of Argentina*, 134 S.Ct. 1198, 1207 (2014). Indeed, conditions precedent such as regulatory approval are a basic feature of contract law.[5] *See, e.g.*, 25 Williston on Contracts § 67:73, at 462 (4th ed. 2013) ("Particular construction or development projects may also require specific governmental or regulatory approvals as conditions precedent to the consummation of the project."); 8 Corbin on Contracts § 31.11, at 99–101 (1999) ("In many contracts it is expressly provided that some act of a third person shall be a condition of a promisor's duty ... [such as a duty] to buy property contingent on a zoning board's approval ....").

It has been implicit in our prior opinions that the absence of FDA or other regulatory approval before the critical date does not prevent a sale or offer for sale from triggering the on-sale bar. For instance, in *Enzo*, we applied the on-sale bar even though the contract for sale covered the buyer's reasonable requirements for "*perform[ing] all preclinical and clinical studies*," by definition before FDA approval, because the "claimed invention, the polynucleotide probe, is a tangible item or product that can be sold or offered for sale." 424 F.3d at 1279, 1282 (emphasis added). Similarly, in *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340 (Fed. Cir. 1998), we affirmed a jury verdict of invalidity based on a sale even though the product sold

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[5] "A condition precedent is either an act of a party that must be performed or a certain event that must happen before a contractual right accrues or a contractual duty arises." 13 Williston on Contracts § 38:7, at 434–37 (4th ed. 2013); *see also id.* § 38:7, at 434–46; Restatement (Second) of Contracts § 224 (1981); 2 Anderson U.C.C. § 2-301:11, at 149–52 (3d ed. 2013); 8 Corbin on Contracts §§ 30.6–30.7, at 9–15 (1999).

was subject to regulatory approval. There was no majority opinion, but through two separate individual opinions a majority of the panel held that the on-sale bar applied. *Id.* at 1354 n.4. One opinion explicitly addressed the patentee's argument that the offer to sell did not trigger the statutory bar because "FDA approval had not been obtained" before the critical date, concluding that "FDA approval is not required before a sale can bar patent rights." *Id.* at 1376 (Mayer, C.J.). The dissent recognized that the majority was rejecting the argument that the product was not on sale because at the time of the sale it was "still being developed [and] tested" for FDA approval. *Id.* at 1357 (Newman, J.). Thus, while the absence of FDA approval may be a relevant consideration depending upon the other circumstances surrounding a transaction relating to a pharmaceutical formulation, the fact that a transaction was subject to regulatory approval would not, absent more, prevent it from being a sale for purposes of the on-sale bar. We do not find that it does so here. This is not a case like *Elan Corp., PLC v. Andrx Pharm., Inc.*, 366 F.3d 1336 (Fed. Cir. 2004), where the purported offer concerned a product when and if it had been developed, and there was no price or quantity term. *Id.* at 1341.

Helsinn also argues that, even if the agreement of sale for the 0.25 mg dose could be an invalidating sale, the agreement was uncertain because it covered the 0.25 mg dose, the 0.75 mg dose, and both doses. Helsinn is correct that the agreement covered either dose or both doses. Under established contract law, even if the agreement had given MGI, as the purchaser, the option of choosing between the two doses, as opposed to making the decision

dependent on actions of third party regulators, there would still be a binding agreement.[6]

In any event, here there is no ambiguity introduced by the provision for the purchase of either or both doses. This contract is indistinguishable from a situation involving two otherwise identical contracts, one covering the 0.25 mg dose and the other covering the 0.75 mg dose, each contingent on FDA approval. It is clear that these two hypothetical agreements would individually trigger the on-sale bar for the 0.25 mg dose and the 0.75 mg dose, respectively. It cannot be that combining them into a single agreement somehow thwarts application of the on-sale bar. We see no valid reason based in contract law, patent law, or otherwise, to distinguish between a single agreement that covers two potential products—like the one between Helsinn and MGI—and two separate agreements, one for each product.

Our en banc decision in *Medicines* also made clear that the offer or contract for sale must unambiguously place *the invention* on sale, as defined by the patent's claims. 827 F.3d at 1374. As discussed below, that is clearly the case here. The Supply and Purchase Agreement described the palonosetron formulation in detail and Helsinn does not assert that the 0.25 mg dose described in the Supply and Purchase Agreement does not embody the asserted claims of the patents-in-suit. The fact that the contract made the selection of which doses to supply contingent on regulatory approval did not create an ambiguity

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[6] *See, e.g.*, 1 Corbin on Contracts § 4.6 (citing *Dolly Parker Motors, Inc. v. Stinson*, 245 S.W.2d 820 (Ark. 1952); *Delaney v. Shellabarger*, 353 P.2d 903 (Nev. 1960); *Langer v. Lemke*, 49 N.W.2d 641 (N.D. 1951); *Calder v. Third Judicial Dist. Court*, 273 P.2d 168 (Utah 1954)); *C.W. Hull Co. v. Westerfield*, 186 N.W. 992, 994 (Neb. 1922).

with respect to whether what was on sale fell within the bounds of the patents' claims.

At oral argument for the first time, Helsinn contended that applying the on-sale bar would be unfair because it would distinguish between vertically-integrated manufacturers that have in-house distribution capacity and smaller entities like Helsinn that must contract for distribution services from a third party. Helsinn asserts that *Medicines* stands for the proposition that we should not allow commercial activities to be invalidating if those same activities could be performed in-house without triggering the on-sale bar. Such a broad principle would largely eviscerate the on-sale bar provision except as to sales to end users; that was not the holding of *Medicines*. There we concluded that "stockpiling," including purchases from a supplier, "does not trigger the on-sale bar." 827 F.3d at 1374. We also expressed concern over a policy of "penalizing a company for relying, by choice or by necessity, on the confidential services of a contract manufacturer." *Id.* at 1378. But the concern that *Medicines* focused on is not applicable here. Helsinn did not contract for MGI's confidential marketing or distribution services as Medicines contracted for Ben Venue's confidential manufacturing services. Instead, the Supply and Purchase Agreement between Helsinn and MGI unambiguously contemplated the sale by Helsinn of MGI's requirements of the claimed invention.

It is clear that the Supply and Purchase Agreement constituted a commercial sale or offer for sale for purposes of § 102(b) as to the asserted claims of the '724, '725, and '424 patents.

II

We next address whether the AIA changed the meaning of the on-sale bar under 35 U.S.C. § 102 so that there was no qualifying sale as to the '219 patent. The parties agree that the '219 patent is governed by the AIA. *See* 35 U.S.C. § 102(a)(1); AIA, Pub. L. No. 112-29, § 3(n), 125 Stat. 284, 293 (2011).

Before the AIA, § 102(b) barred the patentability of an invention that was "patented or described in a printed publication in this or a foreign country or in public use or *on sale* in this country, more than one year prior to the date of the application for patent." 35 U.S.C. § 102(b) (2006) (emphasis added). Under that earlier provision, we concluded that, although confidentiality weighs against application of the on-sale bar, *see Medicines*, 827 F.3d at 1376, 1377 n.2, that fact alone is not determinative.[7] For instance, in *In re Caveney*, a British company offered to sell the claimed invention to an American company that

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[7] *See, e.g.*, *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998) (stating that "an inventor's own prior commercial use, albeit kept secret, may constitute a public use or sale under § 102(b), barring him from obtaining a patent"); *J.A. LaPorte, Inc. v. Norfolk Dredging Co.*, 787 F.2d 1577, 1581–83 (Fed. Cir. 1986) (stating that the on-sale bar "is not limited to sales by the inventor or one under his control, but may result from activities of a third party" and rejecting the argument that "secret commercialization by a third party" is not invalidating since "the invention . . . was discoverable from the device which was sold" and the "device . . . embodie[d] the invention" (emphasis omitted)); *In re Caveney*, 761 F.2d 671, 675 (Fed. Cir. 1985) (rejecting the argument that a secret sale by a third party was not invalidating because "sales or offers by one person of a claimed invention will bar another party from obtaining a patent"); *see also* 2 R. Carl Moy, Moy's Walker on Patents § 8:228 (4th ed. 2016) ("[E]ven a private sale or offer for sale can be a barring event."); 3 John Gladstone Mills III et al., Pat. L. Fundamentals § 10:12 (2d ed. 2017) ("An invention is 'on sale' even though the only sale was a 'private' one.").

would be its exclusive seller in the United States before the critical date. *In re Caveney*, 761 F.2d 671, 673–74 (Fed. Cir. 1985). The court rejected the argument that a sale or offer for sale did not trigger the on-sale bar when it had been "kept secret from the trade," concluding that "sales or offers by one person of a claimed invention . . . bar another party from obtaining a patent if the sale or offer to sell is made over a year before the latter's filing date." *Id.* at 675.

By enacting the AIA, Congress amended § 102 to bar the patentability of an "invention [that] was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." 35 U.S.C. § 102(a)(1) (emphasis added).

Teva and various amici assert that by reenacting the existing statutory term, "on sale," Congress did not change the meaning of the on-sale bar or disturb settled law. Helsinn, the government, and other amici argue that the AIA changed the law by adding the "otherwise available to the public" phrase. They argue that the on-sale bar now does not encompass secret sales and requires that a sale make the invention available to the public in order to trigger application of the on-sale bar. Apart from the additional statutory language, this argument primarily relies on floor statements made by individual members of Congress. While recognizing that such floor statements are typically not reliable as indicators of congressional intent, see, e.g., *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568, (2005), they argue that here we should look to the floor statements to determine the meaning of the provision. These floor statements include material such as the following:

> [S]ubsection 102(a) was drafted in part to do away with precedent under current law that *private offers for sale* or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art. That will no longer be the case.

157 Cong. Rec. 3415 (2011) (remarks of Sen. Leahy) (emphasis added).

> [T]he current on-sale bar imposes penalties not demanded by any legitimate public interest. There is no reason to fear 'commercialization' that merely consists of a *secret sale or offer for sale* but that does not operate to disclose the invention to the public . . . . The present bill's new section 102(a) precludes extreme results such as these . . . .

157 Cong. Rec. 3424 (2011) (remarks of Sen. Kyl) (emphasis added).[8]

We decline the invitation by the parties to decide this case more broadly than necessary. At most the floor statements show an intent "to do away with precedent under current [§ 102] law," 157 Cong. Rec. 3415 (2011) (remarks of Sen. Leahy). Such precedent had held certain secret

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[8] *See also* 157 Cong. Rec. 3423 (2011) (remarks of Sen. Kyl) ("The word 'otherwise' makes clear that the preceding clauses describe things that are of the same quality or nature . . . . As the committee report notes at page 9, 'the phrase "available to the public" is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it . . . must be publicly available.'"); 157 Cong. Rec. 9782 (2011) (remarks of Sen. Smith) ("[C]ontrary to current precedent, in order to trigger the bar in the new 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date.").

uses to be invalidating under the "public use" prong of § 102(b). Senator Kyl explicitly referenced cases such as *Egbert v. Lippman*, 104 U.S. 333 (1881), *Beachcombers International, Inc. v. Wildewood Creative Products, Inc.*, 31 F.3d 1154 (Fed. Cir. 1994), and *JumpSport, Inc. v. Jumpking, Inc.*, Nos. 05–1182, 05–1196, 05–1197, 2006 WL 2034498 (Fed. Cir. July 21, 2006), and stated that "new section 102(a) precludes extreme results such as these." 157 Cong. Rec. 3424 (2011) (remarks of Sen. Kyl). Each of those cases involved a public use where the invention was not, as a result of the use, disclosed to the public. This public use issue is not before us, and we decline to address it.

The floor statements do not identify any *sale* cases that would be overturned by the amendments. Even if the floor statements were intended to overrule those secret or confidential sale cases discussed above and cited in footnote 7, that would have no effect here since those cases were concerned entirely with whether the existence of a sale or offer was public. Here, the existence of the sale—*i.e.*, the Supply and Purchase Agreement between Helsinn and MGI—was publicly announced in MGI's 8-K filing with the SEC. The 8-K filing also included a copy of the contract for sale as an attachment, albeit partially redacted. Detailed information about palonosetron, its benefits and uses in treating CINV were also disclosed. The statements disclosed the chemical structure of palonosetron and specified that the covered products were "pharmaceutical preparations for human use in [intravenous] dosage form, containing [palonosetron] as an active ingredient." Supply and Purchase Agreement, *supra*, art.

1.9.[9] And, as described above, the agreements disclosed all the pertinent details of the transaction other than the price and dosage levels.

Helsinn argues that the AIA did more than overrule the "secret sale" cases, and relies on the "otherwise available to the public" language in the statute and the floor statements. Helsinn argues that those statements suggest that the on-sale bar does not apply unless the sale "disclose[s] the invention to the public" before the critical date. 157 Cong. Rec. 3424 (2011) (remarks of Sen. Kyl). It urges that since the 0.25 mg dose was not disclosed, the invention was not disclosed and the on-sale bar does not apply. The suggestion is that Congress required that the details of the claimed invention be publicly disclosed before the on-sale bar is triggered.

Requiring such disclosure as a condition of the on-sale bar would work a foundational change in the theory of the statutory on-sale bar. Indeed, the seminal Supreme Court decision in *Pennock* addressed exactly such a situation[10]—

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[9] The joint April 10, 2001 press release stated that "[p]alonosetron is a potent and selective 5-HT3 antagonist with an extended half-life, in Phase 3 development for the prevention of chemotherapy-induced nausea and vomiting (CINV)." MGI Pharma Inc., Current Report (Form 8-K) Ex. 99.5, at 1 (Apr. 25, 2001). It also disclosed that, once launched, it would "be one of four products competing in the $1 billion North American market for 5-HT3 antagonists . . . [and its] extended half-life . . . as compared to the other agents and the results of Phase 2 trials assessing efficacy beyond 24 hours differentiate[] palonosetron from the three currently marketed 5-HT3 antagonists indicated for CINV." *Id.* at 2.

[10] *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829) ("If an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention; if he should for a long period of years

the public sale of an item but the withholding from "the public the secrets of [the] invention." *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829). Failing to find such a sale invalidating, said the Court, "would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries." *Id.*

So too under our cases, an invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale is made public. Our cases explicitly rejected a requirement that the details of the invention be disclosed in the terms of sale. *See RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1060 (Fed. Cir. 1989), *overruled in part on other grounds by Grp. One*, 254 F.3d at 1048 (rejecting the argument "that the bid documents themselves must disclose the invention with respect to all claim elements" since that is "clearly not legally correct" and there can be "a definite offer for sale or a sale of a claimed invention even though *no* details are disclosed").

A primary rationale of the on-sale bar is that publicly offering a product for sale that embodies the claimed invention places it in the public domain, regardless of when

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retain the monopoly, and make, and sell his invention publicly, and thus gather the whole profits of it, relying upon his superior skill and knowledge of the structure; and then, and then only, when the danger of competition should force him to secure the exclusive right, he should be allowed to take out a patent, and thus exclude the public from any farther use than what should be derived under it during his fourteen years; it would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries.").

or whether actual delivery occurs.[11] The patented product need not be on-hand or even delivered prior to the critical date to trigger the on-sale bar.[12] And, as previously noted, we have never required that a sale be consummated or an offer accepted for the invention to be in the public domain and the on-sale bar to apply, nor have we distinguished sales from mere offers for sale.[13] We have also not re-

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[11] *See, e.g., Pfaff*, 525 U.S. at 64 ("§ 102 of the Patent Act serves as a limiting provision, both excluding ideas that are in the public domain from patent protection and confining the duration of the monopoly to the statutory term .... A similar reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar."); *Merck & Cie*, 822 F.3d at 1355 n.4 ("One of the primary purposes of the on-sale bar is to prohibit the withdrawal of inventions that have been placed into the public domain through commercialization." (internal quotation marks omitted) (quoting *Abbott Labs. v. Geneva Pharm., Inc.*, 182 F.3d 1315, 1319 (Fed. Cir. 1999))); *J.A. LaPorte*, 787 F.2d at 1583 ("The date of the purchase agreement is, therefore, the effective date on which the invention became part of the public domain. That delivery of the device embodying the invention occurred later is immaterial.").

[12] *See, e.g., Pfaff*, 525 U.S. at 58 (applying the on-sale bar where the sale order was not filled until after the critical date); *STX, LLC v. Brine, Inc.*, 211 F.3d 588 (Fed. Cir. 2000) (same); *Buildex Inc. v. Kason Indus., Inc.*, 849 F.2d 1461 (Fed. Cir. 1988) ("Proof of delivery before the critical date would have been conclusive in this case, but it is not necessary to holding that the device was on sale before then."); *Robbins Co. v. Lawrence Mfg. Co.*, 482 F.2d 426 (9th Cir. 1973) ("A simple placing on sale is sufficient to establish the 'on sale' defense—even an executory contract under which the patented matter is delivered after the critical date.").

[13] *See, e.g., Pfaff*, 525 U.S. at 67 ("[A]cceptance of the purchase order prior to April 8, 1981, makes it clear that ... an offer had been made."); *Merck & Cie*, 822 F.3d at 1352 ("An offer to sell is sufficient to raise the on-sale bar, regardless of whether that sale is ever consummated."); *Hamilton Beach Brands, Inc. v. Sunbeam Prods., Inc.*,

quired that members of the public be aware that the product sold actually embodies the claimed invention. For instance, in *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315 (Fed. Cir. 1999), at the time of the sale, neither party to the transaction knew whether the product sold embodied the claimed invention and had no easy way to determine what the product was. *Id.* at 1317–18.

Thus, our prior cases have applied the on-sale bar even when there is no delivery, when delivery is set after the critical date, or, even when, upon delivery, members of the public could not ascertain the claimed invention. There is no indication in the floor statements that these members intended to overrule these cases. In stating that the invention must be available to the public they evidently meant that the public sale itself would put the patented product in the hands of the public. Senator Kyl himself seems to have agreed with this proposition, stating explicitly that

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726 F.3d 1370, 1374, 1377 (Fed. Cir. 2013) ("An actual sale is not required for the activity to be an invalidating commercial offer for sale."); *Cargill*, 476 F.3d at 1370 ("There is no requirement that the sale be completed."); *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328 (Fed. Cir. 2001) ("An offer for sale does not have to be accepted to implicate the on sale bar."); *A.B. Chance Co. v. RTE Corp.*, 854 F.2d 1307, 1311 (Fed. Cir. 1988) ("A single offer to sell is enough to bar patentability whether or not the offer is accepted."); *Buildex*, 849 F.2d at 1464 ("It is not necessary that a sale be consummated for the bar to operate."); *In re Theis*, 610 F.2d 786, 791 (CCPA 1979) ("For § 102(b) to apply, it is not necessary that a sale be consummated."); *Mfg. Research Corp. v. Graybar Elec. Co.*, 679 F.2d 1355, 1362 (11th Cir. 1982) ("The statutory on sale bar applies when the invention that is the subject of a patent application is merely offered for sale; there is no requirement that a sale be consummated before the statutory bar attaches.").

"once a product is sold on the market, any invention that is inherent to the product becomes publicly available prior art and cannot be patented." 157 Cong. Rec. 3423 (2011) (remarks of Sen. Kyl).[14] There are no floor statements suggesting that the sale or offer documents must themselves publicly disclose the details of the claimed invention before the critical date. If Congress intended to work such a sweeping change to our on-sale bar jurisprudence and "wished to repeal . . . [these prior] cases legislatively, it would do so by clear language." *Dir., OWCP v. Perini N. River Assocs.*, 459 U.S. 297 (1983).

We conclude that, after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale. For the reasons already stated, the Supply and Purchase Agreement between Helsinn and MGI constituted a sale of the claimed invention—the 0.25 mg dose—before the critical date, and therefore both the pre-AIA and AIA on-sale bars apply. We do not find that distribution agreements will always be invalidating under § 102(b). We simply find that this particular Supply and Purchase Agreement is.

III

We finally address whether the invention was ready for patenting as of the critical date of January 30, 2002.

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[14] Senator Kyl quoted our anticipation decision in *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373 (Fed. Cir. 2002). "Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." 157 Cong. Rec. 3423 (2011) (remarks of Sen. Kyl) (internal quotation marks omitted) (quoting *Rosco*, 304 F.3d at 1380).

Under *Pfaff*, there are at least two ways in which an invention can be shown to be ready for patenting: "by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." *Pfaff*, 525 U.S. at 67–68. We conclude that the invention here was ready for patenting because it was reduced to practice before the critical date, and we need not address the alternative enablement approach, not addressed by the district court.[15]

A. Reduction to Practice

An invention is reduced to practice when "the inventor (1) constructed an embodiment . . . that met all the limitations and (2) determined that the invention would work for its intended purpose." *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1373 (Fed. Cir. 2008) (internal quotation marks and citations omitted) (citing *Z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1352 (Fed. Cir. 2007)). Reduction to practice occurs if "the claimant had possession of the subject matter of the [claim] and that it was shown or known to work for its intended purpose."[16] *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 659 F.3d 1186, 1193 (Fed. Cir. 2011); *accord Sanofi-Aventis v. Pfizer Inc.*, 733 F.3d 1364 (Fed. Cir. 2013).

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[15] *See* J.A. 130 n.53.

[16] *See, e.g., Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 997 (Fed. Cir. 2007) (citing to *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563 (Fed. Cir. 1996), a case that addresses ready for patenting in the priority context, for the ready for patenting standard in the context of the on-sale bar).

Before trial, the parties stipulated that they would contest ready for patenting "only with respect to the limitations and intended uses of 'reducing emesis or reducing the likelihood of emesis' and 'to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting' of the asserted claims" and not "for any other reason." J.A. 26081. Thus, for instance, it is uncontested that the formulation had been made and was stable prior to the critical date. Accordingly, the only issue with respect to ready for patenting before the district court and on appeal is whether Helsinn had determined that the invention would work for its intended purpose, which, according to the claims, is "reducing the likelihood" of emesis and CINV.

Our cases distinguish between the standard required to show that a particular invention would work for its intended purpose and the standard that governs FDA approval of new drugs, including the various stages of clinical trials. *See, e.g.*, *Scott v. Finney*, 34 F.3d 1058, 1063–64 (Fed. Cir. 1994) (addressing reduction to practice in the priority context). In patent law, the requisite testing, if any, for showing that an invention will "work for its intended purpose" varies depending on "the character of the invention," including the claim language and the "nature and complexity of the problem" the invention seeks to solve. *Id.* at 1061–62; *see also Slip Track Sys., Inc. v. Metal-Lite, Inc.*, 304 F.3d 1256, 1265 (Fed. Cir. 2002). Generally there must be some "demonstration of the workability or utility of the claimed invention." *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 997 (Fed. Cir. 2007). This must show that the invention works for its intended purpose "beyond a probability of failure" but not "beyond a possibility of failure." *Scott*, 34 F.3d at 1062. "[L]ater refinements do not preclude reduction to practice, [and] it is improper to conclude that an

invention is not reduced to practice merely because further testing is being conducted." *Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1367 (Fed. Cir. 2008).

Approval of a new drug by FDA, however, is a more demanding standard than that involved in the patents-in-suit. The patents here make no reference to FDA standards and broadly claim a palonosetron formulation for reducing the likelihood of emesis and CINV. For FDA approval, however, an applicant must submit, *inter alia*, "adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use" and "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed." 21 U.S.C. § 355(d). This requires "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." *Id.* This is understood to be "a rigorous standard." *Ams. for Safe Access v. DEA*, 706 F.3d 438, 451 (D.C. Cir. 2013).

Here, the district court based its finding that the invention was not reduced to practice before the critical date on insufficient testing for Helsinn to have "determined that the invention would work for its intended purpose." J.A. 159. The district court appeared to believe that Teva needed to meet the FDA standard, which requires finalized reports with fully analyzed results from successful Phase III trials. This is clear from the district court's

reliance on the testimony of Helsinn's expert who "referred to FDA standards in forming his opinions in this case" and stated that FDA "articulated a statistical framework for being able to really know from the [clinical trial] data ... that a drug is working." J.A. 148. Throughout its opinion the district court found lack of reduction to practice for failure to establish "efficacy" under FDA standards, and the lack of fully analyzed Phase III studies as required by FDA. J.A. 159. The district court was influenced particularly by the fact that FDA found the so-called Study 2330 insufficient to demonstrate efficacy.[17] *See, e.g.*, J.A. 34, 48–50, 56, 147, 151, 154–55.

The district court clearly erred by applying too demanding a standard. The completion of Phase III studies and final FDA approval are not pre-requisites for the invention here to be ready for patenting. The evidence is overwhelming that before the critical date of January 30, 2002, it was established that the patented invention would work for its intended purpose of reducing the likelihood of emesis.

- The 1995 report from Study 2330 demonstrated that three different doses, including the 0.25 mg dose, produced statistically significant results at the 5% level for the median time it took patients to experience an emetic episode after administration of palonosetron. While this study did not show statistical significance for complete control of emesis or CINV for 24

[17] FDA found Study 2330 insufficient on its own to support Phase III trials since, "[w]hen compared to the lowest doses (0.3 and 1 mcg/kg) only the 30 mcg/kg dose was statistically significant; a significant dose response trend was not evident." J.A. 10907. We view this as irrelevant to whether the invention was ready for patenting.

hours, complete control is not a claim requirement. The invention is for reducing the likelihood of emesis, not necessarily completely preventing it, and the statistical significance for mean time to failure demonstrates that the product reduced the likelihood of emesis. Indeed, the Study 2330 final report concluded that the relevant dose of palonosetron "was effective in suppressing" CINV. J.A. 1636. Under our cases this is sufficient to establish that the invention here would work for its intended purpose of reducing the likelihood of CINV. *See, e.g.*, *Z4 Techs.*, 507 F.3d at 1352 (concluding that the intended purpose of the invention at issue was to reduce piracy, not to completely stop its occurrence).

- Giorgio Calderari, one of the named inventors of the patents-in-suit, characterized the results of the Phase II trial, Study 2330, as "yes, the product was showing some efficacy clearly." J.A. 524.

- Minutes from a July 1998 meeting of Helsinn's palonosetron team indicated that their "proposal [wa]s to test *effective* doses seen in Phase 2," including the 0.25 mg dose. J.A. 1424 (emphasis added).

- The proposed protocols for Phase III trials that Helsinn submitted to FDA in November 1999 stated that the "[r]esults achieved in Phase II CINV studies suggest that palonosetron is safe and effective in preventing nausea and vomiting following emetogenic chemotherapy," J.A.

3846, and "[d]ata from this study clearly demonstrate that the 3 μg/kg dose of palonosetron is the minimal effective dose in preventing CINV," J.A. 3851.

- On September 14, 2000, Helsinn announced in a press release that "Phase II trials [had] demonstrated the efficacy of Palonosetron in the prevention of emesis with no significant side effects." J.A. 9983.

- On January 7, 2002, Helsinn prepared preliminary data tables analyzing the results from the first Phase III trial.[18] "[T]he preliminary data for Complete Response, which is the primary efficacy outcome measure for acute CINV, was 81.0% (153/189) for palonosetron 0.25 mg." J.A. 81. This means that 81% of patients who received the 0.25 mg dose of palonosetron experienced relief from CINV for 24 hours. As one of the named inventors of all four patents explained, these data showed that the 0.25 mg dose of palonosetron "reduced the likelihood of CINV in those subjects." J.A. 593.

- In a 2007 declaration submitted to overcome an initial rejection by the examiner during prosecution, Giorgio Calderari and four of the other named inventors of the patents-in-suit stated

[18] Even though the purported sale or offer for sale occurred before these data tables were prepared, post-contract developments are relevant such that even if an invention is not ready for patenting at the time of the offer or sale, it may become so before the critical date and thereby trigger application of the on-sale bar, a point to which both parties agreed at oral argument.

that "[t]he formulations . . . were completed sometime before March 24, 1999" and that they "had invented and were in possession of all of the subject matter currently claimed . . . as of March 24, 1999." J.A. 1411–12. This was clarified at trial as referring to the claimed invention, *i.e.*, "a pharmaceutically stable solution for reducing emesis or reducing the likelihood of emesis." J.A. 527 (154:16–22; 156:1–9).

- In a 2010 declaration corresponding to another related palonosetron patent application,[19] Sergio Cantoreggi and two named inventors of the '724, '725, and '424 patents submitted a declaration stating that they "had conceived the invention . . . , and reduced it to practice, before November 16, 2001," J.A. 2921 ¶ 2, and "had conceived the idea to use palonosetron for the treatment of acute and delayed-onset CINV, and had conducted clinical trials in humans to test this idea, at least as early as October 2, 2001," J.A. 2921 ¶ 3. The declaration concluded that "[m]ost important, [they] had successfully tested the method in human patients, and [they] had done so before October 2, 2001 (the date the [Phase III] study was completed)."

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[19] The patent application claimed a method of treating CINV with the 0.25 mg dose: "A method of treating chemotherapy or radiotherapy-induced acute and delayed emesis in an adult human for five days after an emesis inducing chemotherapy or radiotherapy event, comprising administering to said human a single dose of a treatment-effective amount of about 0.25 mg of palonosetron in the form of palonosetron hydrochloride prior to said emesis-inducing event, without administering any further palonosetron during said give day period." J.A. 2922.

J.A. 2923 ¶ 18. The district court found that these statements in the 2010 declaration "were literally true." J.A. 158.

These results consistently showed that the invention worked for its intended purpose, from the final report for the 1995 Phase II trial to the preliminary results in January 2002 from a Phase III trial. Under the district court's unduly restrictive standard, Helsinn could not have filed a valid patent application before the critical date of January 30, 2002. Such a standard would preclude the filing of meritorious patent applications in a wide variety of circumstances. The evidence that the formulation was ready for patenting is overwhelming, and the District Court's contrary conclusion—applying the wrong standard—was clearly erroneous. There is simply no tenable argument that, before the critical date, Helsinn was unable to file a patent application that met the requirements of 35 U.S.C. § 112.[20]

The district court and Helsinn on appeal rely on our decision in *Omeprazole* to argue that the results from Phase III trials must be analyzed in order to draw a valid conclusion regarding whether the invention works for its

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[20] *See Space Sys./Loral, Inc. v. Lockheed Martin Corp.*, 271 F.3d 1076 (Fed. Cir. 2001) ("To be 'ready for patenting' the inventor must be able to prepare a patent application, that is, to provide an enabling disclosure as required by 35 U.S.C. § 112 .... [W]hen development and verification are needed in order to prepare a patent application that complies with § 112, the invention is not yet ready for patenting."); *Clock Spring, L.P. v. Wrapmaster, Inc.*, 560 F.3d 1317 (Fed. Cir. 2009) ("By filing the 1992 [patent] application, the inventors represented that the invention was then ready for patenting .... "); *see also In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995) ("FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws.").

intended purpose. *See Omeprazole*, 536 F.3d 1361. But there is no general rule that Phase III trials must be completed before a product is ready for patenting, just as there is no general rule that Phase III trials are irrelevant. Each case must be decided based on its own facts. And this case is not like *Omeprazole*. In *Omeprazole*, there was significant uncertainty going into Phase III trials regarding whether the formulation would "solve the twin problems of *in vivo* stability and long-term storage" that had been identified *after* Phase II trials. *Id.* at 1373 (internal quotation marks omitted). Indeed, between Phase II and Phase III the researchers needed to attempt "a number of modifications to the Phase II formulation" since achieving the "two goals seemingly conflicted." *Id.* Here, of course, there was no similar need to modify the formulation in between the Phase II and Phase III trials, as Helsinn stipulated to the formulation's stability.

We conclude that the invention was reduced to practice and therefore was ready for patenting before the critical date.

CONCLUSION

We hold that the asserted claims, claims 2 and 9 of the '724 patent, claim 2 of the '725 patent, claim 6 of the '424 patent, and claims 1, 2, and 6 of the '219 patent, are invalid under the on-sale bar.

REVERSED.

APPENDIX C

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

No. 11-3962 (MLC)

HELSINN HEALTHCARE S.A., et al.,
Plaintiffs,

v.

DR. REDDY'S LABORATORIES LTD.,et al.,
Defendants.

March 3, 2016

SUPPLEMENTAL OPINION

COOPER, District Judge.

This is an action arising under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A). Plaintiffs, Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively, "plaintiffs"), are assignees of U.S. Patents No. 7,947,724 ("the '724 patent"), No. 7,947,725 ("the '725 patent"), No. 7,960,424 ("the '424 patent"), and No. 8,598,219 ("the '219 patent"). The four patents-in-suit are listed in the FDA "Orange Book" as covering plaintiffs' product Aloxi®, which is a pharmaceutical composition containing the active ingredient palonosetron. The version of Aloxi® currently marketed by plaintiffs is an

intravenous solution with approved indications for preventing or treating cancer chemotherapy-induced nausea and vomiting.

Plaintiffs brought this action, and related consolidated actions, against generic drug manufacturers, Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc. ("DRL"), Sandoz, Inc. ("Sandoz"), Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. ("Teva"). Plaintiffs alleged that each group of defendants had filed an Abbreviated New Drug Application ("ANDA") containing so called "Paragraph IV" certifications asserting that the claims of the patents-in-suit were invalid and/or not infringed. The asserted claims are claims 2 and 9 of the '724 patent, claim 2 of the '725 patent, claim 6 of the '424 patent, and claims 1, 2, 6, and 7 of the '219 patent. The pertinent limitations of the first three patents are "reducing emesis . . . ," the "0.05 mg/mL" concentration, and "EDTA." The pertinent limitations of the '219 patent are "reduce . . . cancer chemotherapy-induced nausea and vomiting," "0.25 mg" dose in "5 mL . . . solution," and "EDTA."

Defendant Sandoz was dismissed from the action by consent, on December 31, 2014. (Dkt. 247.)[1] The Court is-

[1] The Court will cite to the documents filed in this case in the Electronic Case Filing System ("ECF") by referring to the docket entry numbers by the designation of "dkt." References to docketed materials are to ECF pagination. The two later-filed actions that have been consolidated into this lead case are Civil Action No. 11-5579 and Civil Action No. 13-5815. Copies of the four patents-in-suit are attached as exhibits to the pleadings, and are trial exhibits. We will simply cite to the patents by page or column and line number. Those patents are

sued a Memorandum Opinion construing certain preamble language in the '219 patent claims, on April 22, 2015. (Dkt. 290.) An 11-day bench trial was conducted in June 2015, with closing arguments presented on August 12, 2015. (Dkts. 320, 322, 324, 326, 328, 330, 331, 337, 340, 342, 344, and 353.) Defendant DRL was dismissed on stipulation on October 16, 2015. (Dkt. 355.)[2] Thus, the current parties in this case are plaintiffs and Teva.

Teva asserts that the asserted claims of each of the four patents-in-suit are invalid as obvious under 35 U.S.C. § 103.[3] Teva further asserts invalidity of those patents under the on-sale bar provision of 35 U.S.C. § 102. The on-sale bar issue presents not only underlying factual questions, but also a statutory interpretation question addressing the amended text of § 102(a)(1) under the America Invents Act ("AIA"), Pub. L. No. 112-29 (2011). Teva also raises a written description claim against those patents under 35 U.S.C. § 112. Plaintiffs oppose each of

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trial exhibits numbered as follows: '724 patent (DTX-0069), '725 patent (DTX-0070), '424 patent (DTX-0001 and DTX-0071), and '219 patent (DTX-0268).

[2] DRL and plaintiffs have a related action, actively pending in this Court, pertaining to the '724 patent and DRL's pending 505(b)(2) New Drug Application under 21 U.S.C. § 355(b)(2). See Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al., Civil Action No. 12–2867. In that case, the Court issued a Memorandum Opinion and Order on April 2, 2015, construing the '724 claim term "a chelating agent." (Civ. Action No. 12–2867, dkt. 91 (Order) and dkt. 92 (SEALED Mem. Op.).)

[3] Teva has advised that it will not appeal the ruling of this Court that the patents-in-suit are valid under 35 U.S.C. § 103 (obviousness). This Court will issue a separate Supplemental Opinion providing further rulings on that issue as necessary.

Teva's points on those issues, asserting that the patents are valid and enforceable.

There is also an infringement issue. Teva filed one consolidated ANDA, seeking approval for products at two different dose levels (0.25 mg and 0.075 mg), and two different treatment indications (chemotherapy-induced nausea and vomiting ("CINV") for the 0.25 mg dose, and post-operative nausea and vomiting ("PONV") for the 0.075 mg dose). The concentration of both proposed Teva products is 0.05 mg/ml, because the 0.25 mg dose solution is 5 ml and the 0.075 mg dose solution is 1.5 ml. The asserted '219 patent claims only specify a 0.25 mg dose, in a 5 ml volume (i.e., concentration 0.05 mg/ml), for CINV. Plaintiffs assert that if the '219 claims are held to be valid, those claims are infringed by Teva's ANDA filing itself, according to the Hatch-Waxman Act, and therefore both generic products applied for in Teva's ANDA must infringe and be enjoined. Teva disputes plaintiffs' legal position and seeks a declaration that its 0.075 mg dose PONV product will not infringe the asserted '219 patent claims.

The Court issued a Memorandum Opinion on November 13, 2015, and entered judgment declaring that:

(1) the asserted claims of the '724, '725, and '424 patents are valid and are infringed by both Teva's proposed 0.25 mg and 0.075 mg generic products;

(2) the asserted claims of the '219 patent are valid and are infringed by Teva's proposed 0.25 mg generic product; and

(3) the asserted claims of the '219 patent are valid and are not infringed by Teva's proposed 0.075 mg generic product.

(Dkt. 360; dkt. 361.)

This Supplemental Opinion constitutes the Court's findings of fact and conclusions of law on the issues of the on-sale bar under 35 U.S.C. § 102, statutory interpretation of the on-sale bar after the passage of the American Invents Act under 35 U.S.C. § 102(a)(1), written description under 35 U.S.C. § 112, and infringement under 35 U.S.C. § 271. The Court now makes the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a)(1).

1. FINDINGS OF FACT

A. Medical treatment for emesis

Medical science has long recognized that the human body has an elaborate and multifaceted defense system against trauma and toxins. (Dkt. 328 at 29.) Part of that defense system is called emesis, referring generally to the reflexive reaction experienced as nausea and vomiting. (Id. at 27, 31-32.) Its purpose is essentially to get rid of toxins in the body. (Id. at 26.)

The parties presented undisputed medical background information on the scientific field of the claimed inventions. (Id.; see also dkt. 320; dkt. 324; dkt. 326; dkt. 331; dkt. 337; dkt. 340; dkt. 342; dkt. 344.) For example, Teva's expert clinician Dr. David Frame provided a basic overview of the mechanisms in the body that lead to emesis, at least as related to chemical stimuli.[4] As he explained, the gastrointestinal tract and the brain are the

[4] Dr. Frame explained that he uses the term "emesis" to refer to vomiting, as distinguished from nausea. (See dkt. 328 at 31.) Other

two primary systems involved in creating emesis. (Dkt. 328 at 25–26.) If a person ingests a toxin directly into the stomach, or if a toxin is injected into the blood, the noxious substances go into the GI tract. (Id. at 26.) The GI tract then releases certain molecules called neurotransmitters. (Id.) Those neurotransmitters will bind to receptors, causing signals to transmit up a nerve called a vagal nerve that leads to a specific spot located in the brain but just outside the blood-brain barrier (the trigger zone or essentially the vomiting center). (Id.) When those neurotransmitter signals arrive there, they will activate one or more neurotransmitters that will carry the signal back down the vagal nerve to the GI tract and produce the contractions of nausea and vomiting. (Id. at 27.)

Scientists have identified approximately 20 to 30 types of neurotransmitters that play a role in prompting the emesis reaction. (Id. at 28.) Those neurotransmitters bind to cells called receptors, found in various places in the body. (Id. at 28–29.) In other words, several different neurotransmitters and corresponding receptors are involved in most causes of nausea and vomiting. (Id. at 29.) Also, depending on what kind of toxic stimulus is introduced, there may be different amounts and types of neurotransmitters activated, and different locations within the body where the corresponding receptors are concentrated. (Id. at 28–29.) All of this is part of that elaborate defense system against various toxic substances that is inherent in the body. (Id. at 26, 29.)

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witnesses and some of the prior art would use the term "emesis" more broadly to refer to nausea and vomiting. (See, e.g., dkt. 331 at 20.) We use the term in that broader sense, except when referring to testing results that pinpoint those aspects separately.

One of the neurotransmitters known to play a role in causing emesis is serotonin (5-hydroxytryptamine). (Id. at 28.) It can bind to many different types of receptors, but the one that it binds to that is most responsible for nausea and vomiting is a specific "hydroxytryptophan" receptor, called the 5-HT3 receptor. (Id. at 29.) Indeed, there are different types of hydroxytryptophan receptors, and the number 3 type (the "5-HT3 receptor") is known to be specific in binding with serotonin to release those nausea and vomiting signals. (Id.)

Some of the other types of neurotransmitters known to participate in prompting emesis (with corresponding varieties of receptors) are dopamine and something called Substance P that binds to neurokinin receptors. (Id. at 29, 33.) For this reason, among others, clinicians trying to prevent or treat emesis will often use a multifaceted approach. (Id. at 29.) Instead of relying on just one type of drug product, they will use a combination of therapies. (Id.) The pharmaceutical products used in this effort, that target various receptors and their corresponding neurotransmitters, are referred to as "antagonists." (Id. at 30.) Thus, compounds directed to serotonin and the 5-HT3 receptor are called "serotonin receptor antagonists" or "5-HT3 receptor antagonists." (Id.)

There are also timing and toxin factors in selecting "antiemetic" therapies. For example, some toxins used in medical treatment, or dosage levels of those toxins, are considered "highly emetogenic," whereas others may be considered "moderately emetogenic." (Id. at 148; dkt. 324 at 52.)

It is recognized that the onset and duration of emesis may vary, depending on the situation. (Dkt. 328 at 38.) So antiemetic therapy will look at effects in the immediate

time period after introduction of a toxin, as well as in the succeeding hours and days. (Id.) Those time periods are referred to as the "acute emesis" period for the first 24 hours, and "delayed emesis" thereafter. (Id. at 38–39.) These time periods are a recognized feature of designing and studying antiemetic care.

Another defining concept in the antiemetic field is the distinction between so-called "post-operative nausea and vomiting," or PONV, and "cancer chemotherapy-induced nausea and vomiting," or CINV. (Id.) Both sorts of reactions are encompassed within the general term "emesis," but clinicians typically will select antiemetic therapies with that distinction in mind. (Id.) For example, the claims of the '219 patent-in-suit are directed to "cancer chemotherapy-induced nausea and vomiting." See Section I.B. The claims of the other three patents-in-suit are directed more broadly to "emesis." (Id.)

Aloxi® is the brand name of plaintiffs' antiemetic product, listed in the FDA Orange Book as covered by the four patents-in-suit. The active ingredient in Aloxi® is palonosetron hydrochloride, which is a serotonin antagonist or so-called 5-HT3 antagonist. It is currently marketed in the United States in the form of an intravenous 0.25 mg dose in 5 ml solution (resulting in palonosetron concentration of 0.05 mg/ml). At that dosage, it has FDA-approved indications for preventing CINV in both moderately and highly emetogenic cancer chemotherapy, including delayed CINV with respect to the moderately emetogenic chemotherapy. (DTX-1244-0002.) A later-approved additional indication is at a one-third lower dosage of 0.075 mg for prevention of PONV, but it is not currently marketed in that form. (Id.; dkt 331 at 85.)

The compound Aloxi®, with its label information, received FDA approval on July 25, 2003, after a lengthy new drug application process. See n. 39 infra. The provisional patent application to which the four patents-in-suit claim priority was filed on January 30, 2003. The parties agree that the relevant date for analyzing prior art (as well as for the on-sale bar factual issues) is January 30, 2002. See n. 61 infra. As the discussion in this opinion will demonstrate, the patent validity issues in this case focus heavily upon the history of the Aloxi® drug development process in that time frame.

B. The patents-in-suit

The four patents-in-suit are each named "Liquid Pharmaceutical Formulations of Palonosetron." They are all composition patents. (Dkt. 290 at 2.) There are other patents and patent applications in the same patent family history. (Id.; dkt. 289.)

Each of the patents-in-suit claims priority to the original provisional application date, January 30, 2003, although they have different effective filing dates. (Dkt. 289.) In chronological order of issuance, they are the '724 and '725 patents, issued on May 24, 2011; the '424 patent, issued on June 14, 2011; and the '219 patent, issued on December 3, 2013. (Id.)

All four patents are subject to terminal disclaimer, and will expire no earlier than July 30, 2024. (Dkt. 361 at 3.) The parties agree that the first three patents are subject to the patent provisions in effect prior to enactment of the AIA, and the '219 patent is subject to the AIA for purposes of this case. In fact, the '219 patent was applied for and granted during the pendency of this litigation. (Dkt. 289.) This case was filed on July 8, 2011. (Dkt. 1.) The

effective application date of the '219 patent was May 23, 2013, after the pertinent effective date of the AIA. (Dkt. 289.)

The asserted claims are the '724 patent, claims 2 and 9; the '725 patent, claim 2; the '424 patent, claim 6; and the '219 patent, claims 1, 2, 6, and 7. (Dkt. 174 at 2.) This Court has issued a claim construction opinion that construed the preamble language of the asserted claims to be claim limitations. (Dkt. 290.)

Claim 2 of the '724 patent is representative of the asserted claims of the '724, '725, and '424 patents. Rewritten to incorporate claim 1 of the '724 patent on which it depends, claim 2 states:

> A pharmaceutically stable intravenous solution for reducing emesis or reducing the likelihood of emesis comprising:
>
> a) about 0.05 mg/ml palonosetron or a pharmaceutically acceptable salt thereof, buffered at a pH of from 4.0 to 6.0; and
>
> b) a pharmaceutically acceptable sterile aqueous carrier including a tonicifying effective amount of mannitol and from 0.005 mg/ml to 1.0 mg/ml EDTA.

('724 patent, col. 9, line 27, to col. 10, line 3.)

Asserted claim 1 of the '219 patent, on which asserted claims 2, 6, and 7 of that patent depend, states:

> A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea

> and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:
>
> palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;
>
> from 0.005 mg/mL to 1.0 mg/mL EDTA; and
>
> from 10 mg/mL to 80 mg/mL mannitol,
>
> wherein said formulation is stable at 24 months when stored at room temperature.

('219 patent, col. 10, lines 1–12.)

The written descriptions of the four patents are generally similar. For example, the specification of each patent contains the following sentence, giving the exact dosage and/or concentration appearing in the asserted claims:

> In one particular embodiment the palonosetron is supplied in vials that comprise 5 ml. of solution, which equates to about 0.25 mg of palonosetron at a concentration of about 0.05 mg/ml.

(See '724 patent, col. 4, line 66, to col. 5, line 2; '725 patent (same); '219 patent (same); '424 patent, col. 5, lines 14–17.)

C. Factual chronology

It is necessary to set forth in detail the factual history of the pharmaceutical development process that led to the patents-in-suit, and to the marketing of Aloxi® as their commercial embodiment. That factual history is undisputed, but the parties differ sharply as to the legal conse-

quences of the facts, particularly in analyzing Teva's validity challenges based on both obviousness and the on-sale bar.

An important distinction must be borne in mind when reviewing this factual history. For purposes of the obviousness analysis, the focus must be on the state of the art as publicly known; that is, the published prior art and what a skilled artisan would have known. In fact, the actual process of invention that led to the claimed invention is considered irrelevant under obviousness analysis. See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1364 (Fed. Cir. 2008). In sharp contrast, the legal tests for the on-sale bar require a court to look also at facts that were not public; for example, to determine whether the invention was "ready for patenting" more than one year before the patent application date. See Section II.A.4.

One fact that is pivotal to both the obviousness and the on-sale bar issues is that the provisional application date for all four patents-in-suit was January 30, 2003. (See dkt. 289.) Therefore, the date of January 30, 2002, is the critical date for purposes of the on-sale bar. See 35 U.S.C. § 102, amended by Leahy-Smith America Invents Act, Pub.L. No. 112-29, 125 Stat. 254 (2011). That same date of January 30, 2002, is also the date for obviousness analysis of the published prior art references, as stipulated by the parties. (Dkt. 328 at 240–41.)

Here we set forth both the publicly known and the behind-the-scene facts in recounting this history. In Section II the parties' arguments on their many legal issues are addressed by reference to these facts.

1. Syntex and the genus '333 patent

There was a group of scientists in Palo Alto, California, doing research in a company named Syntex (U.S.A.), Inc. ("Syntex"), beginning in the late 1980's. In May 1991, Syntex filed a patent application that resulted in issuance of U.S. Patent No. 5,202,333 ("the '333 patent") on April 13, 1993. (DTX-0343.)

The '333 patent disclosed "novel compounds which are 5-HT3 receptor antagonists," in particular, "tricyclic 5HT3 receptor antagonists containing a bridged bicyclic amine substituent." (Id., col. 1, lines 9–14.) There were three independent claims and many dependent claims. Claim 1 was to "a compound of Formula I," which was an extremely broad genus-type formula. (Id., col. 34, line 15, to col. 35, line 14.) Independent claim 40 made the following pharmaceutical composition claim:

> A pharmaceutical composition for treating a condition chosen from emesis, a gastrointestinal disorder treatable with prokinetic agents, anxiety/depressive state, and pain, which composition comprises a therapeutically effective amount of a compound of claim 1 in combination with a pharmaceutically acceptable carrier.

(Id., col. 37, lines 10–17.) Independent claim 41 claimed a method for treating a condition chosen from those disorders, "in an animal in need of such treatment." (Id., col. 37, lines 18–24.)

"Emesis" was a defined term in the '333 patent, quoted here in the margin.[5] "Disease" was defined to include "the emesis caused by therapy with agents having emetogenic side effects, in particular by therapy for cancer, such as chemotherapy with cytotoxic agents ...." (Id., col. 4, lines 33–41.) "Treating" was defined to include preventing, inhibiting, or relieving the "disease." (Id., col. 5, lines 33–40.)

The Background of the Invention section of the '333 specification explained serotonin and its receptors, in pertinent part as follows:

> Serotonin, a neurotransmitter with mixed and complex pharmacological characteristics, was first discovered in 1948 and subsequently has been the subject of substantial research. Serotonin, also referred to as ... (5-HT), acts ... on discrete 5-HT receptors ... [which] are presently delineated into three major subclassifications – 5-HT1, 5-HT2 and 5-HT3 .... Receptors of the 5-HT3 subclass ... appear to regulate the release of a variety of neurotransmitters in the gastrointestinal, cardiovascular and central nervous systems.
>
> 5-HT3 receptors are located in high densities on neurons associated with the emetic reflex and drugs which block the interactions of serotonin at the 5-HT3 receptor level, i.e., 5-HT3 receptor antagonists, possess po-

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[5] The '333 written description stated: "'Emesis', for the purposes of this application, will have a meaning that is broader than the normal, dictionary definition and includes not only vomiting, but also nausea and retching." (DTX-0343, col. 4, lines 42–45.)

> tent antiemetic properties. Such antagonists demonstrate utility for counteracting the emetic effects of cancer chemotherapy and radiotherapy.

(Id., col. 1, lines 19–41.)

The parties agree that palonosetron is one of the myriad compounds claimed within Formula I of the '333 patent, although the exact chemical name and structure of palonosetron is not specified.[6] The number of compounds claimed in the '333 patent is not quantified in the patent itself or in any of the trial evidence, but expert testimony at trial indicated that the amount of possible combinations that could be claimed within the patent formula was "huge." (Dkt. 328 at 172.)

The '333 specification reported that the inventors had employed accepted testing methods to determine activity of "the compounds of Formula I" in animals. (DTX-0343, col. 11.) That testing included in vitro assay of rat brain tissue, as well as in vivo testing of anesthetized rats, to measure 5-HT3 "receptor binding affinity" of the compounds. (Id., col. 11, lines 5–11.) It also included in vivo measurement of "anti-emetic activity" of the compounds in reducing emesis induced by a chemotherapy agent (specifically, cisplatin) in ferrets and in dogs. (Id., col. 11, lines 11–35.)

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[6] Teva's formulator expert, Dr. Kirsch, identified this language in the '333 specification as including palonosetron: "Of most interest are the compounds of Formula I in which each p, q and u are 0, and R3 is 1-azabicyclo[2.2.-2]oct-3-yl, in particular wherein one or, when present, both chiral centers possess S configurations." (Dkt. 326 at 189 (quoting DTX-0343, col. 9, lines 23–26).)

As seen in the claim language of the '333 patent, the planned uses of its compounds were not confined to antiemetic treatment. (Id., col. 37, lines 10–26; col. 38, lines 1–7.) Other "diseases" such as gastrointestinal disorders, anxiety, and pain were also listed. (Id., col. 37, lines 18–23.) When discussing administration of the claimed compounds, the '333 specification gave correspondingly broad descriptions of possible routes of administration,[7] dosing levels,[8] and drug concentration formulations,[9] as quoted in

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[7] The '333 specification stated: "In general, compounds of Formula I will be administered as pharmaceutical compositions by one of the following routes: oral, systemic (e.g., transdermal, intranasal or by suppository) or parenteral (e.g., intramuscular, intravenous or subcutaneous)." (DTX-0343, col. 12, lines 25–29.)

[8] The '333 specification addressed dosage of a "pharmaceutically effective amount" as follows:

> A therapeutically effective amount may vary widely depending on the severity of the disease, the age and relative health of the subject, the potency of the compound used and other factors. Therapeutically effective amounts of compounds of Formula I may range from approximately 1.0 nanogram per Kg (ng/Kg) body weight per day to 1.0 mg/Kg body weight per day. Preferably the amount will be approximately 10 ng/Kg/day to 0.1 mg/Kg/day. Therefore, a therapeutically effective amount for a 70 Kg human may range from 70 ng/day to 70 mg/day, preferably 700 ng/day to 7.0 mg/day.

(DTX-0343, col. 12, lines 7–18.)

[9] The '333 specification discussed drug concentration as follows:

> The amount of a compound of Formula I in the composition may vary widely depending upon the type of formulation, size of a unit dosage, kind of excipients and other factors known to those of skill in the art of pharmaceutical sciences. In general, the final composition will comprise from 0.000001% w to 10.0% w of the compound of Formula I, preferably 0.00001% w to 1.0% w, with the remainder being the excipient or excipients. (DTX-0343, col. 12, lines 60–68.)

the margin. Regarding dosage, the specification also stated: "One of ordinary skill in the art of treating such diseases will be able, without undue experimentation and in reliance upon personal knowledge and the disclosure of this application, to ascertain a therapeutically effective amount of a compound of Formula I for a given disease." (Id., col. 12, lines 19–24.)

The '333 patent specification provided Example 13 as "representative pharmaceutical formulations containing a compound of Formula I." (Id., col. 28, lines 55–56.) It included examples for an oral solution, an intravenous solution, and a tablet.

The intravenous formulation in Example 13 was:

Compound of Formula I	10-100mg
Dextrose Monohydrate	q.s. to make isotonic
Citric Acid Monhydrate	1.05 mg
Sodium Hydroxide	0.18mg
Water for Injection	to 1.0ml

(Id., col. 29, lines 6–11.)

The Syntex inventors continued their research involving the compounds claimed in the '333 patent into the mid-1990's, as described next.

2. Roche Syntex further development process

Syntex pursued the development of its '333 patent compounds through several steps in its research process. That research included the laboratory studies referred to in the specification of the '333 patent, and other studies documented in its own internal "formulation books." (Dkt. 320 at 27–28.)

Syntex filed an Investigational New Drug ("IND") application, number 39,797, with the FDA on June 2, 1992. (See PTX-261.0002.) The subject of the IND was investigation of palonosetron hydrochloride, designated RS-25259-197 ("RS-25259"). (See id.)

As Helsinn later stated to the FDA, in summarizing the Syntex preclinical (animal) studies leading to that IND application, "[e]xtensive *in vitro* and *in vivo* pharmacologic studies for palonosetron have been conducted." (DTX-293-0031.) Among the key findings from those studies was that palonosetron "has a high affinity and specificity for 5-HT3 receptors," and "[p]alonosetron is effective in animal modes of chemically induced emesis by both oral and intravenous routes." (Id. at -0031 to -0032.)

The Syntex research under its IND progressed through Phase I and Phase II clinical testing of RS-25259. (See dkt. 320 at 30–32.) The Phase I clinical studies were to determine safety and pharmacokinetics of the palonosetron, by administering it as an intravenous injection to healthy human volunteers. (DTX-0293-0032.) Once the Phase I clinical studies were complete and indicated safety of the drug, Syntex obtained FDA approval and proceeded to Phase II studies, which it worked on through approximately 1995. (Id. at -0032 to -0035; dkt. 320 at 31–32.) The pharmacokinetic data from the Phase I studies also indicated that "[t]he mean plasma elimination half-life . . . was approximately 40 hours in subjects given single IV or oral doses." (DTX-0293-0033.)

Generally, in a Phase II clinical study, the active pharmaceutical ingredient ("API") is administered to actual patients, to continue assessing safety but also to start determining effective dosage levels in humans. (See dkt. 320 at 31.) If Phase II studies are completed and accepted by

the FDA, the applicant may request to proceed to Phase III, which is typically a large-scale study conducted with an actual pharmaceutical formulation, including excipients and packaging, involving patients in many locations. In Phase III, the safety and efficacy of the formulation is measured in the patients, and stability and manufacturing quality of the product are tested in samples. (Id.)

Syntex was acquired by the Roche pharmaceutical organization ("Roche") at some time prior to 1995. (Dkt. 320 at 127.) Syntex was then known as Roche Syntex, or officially Roche Palo Alto LLC. (See id.; '724, '725, '424, and '219 patents, page 1.)

Several Phase II clinical trials to evaluate safety and efficacy of palonosetron hydrochloride were conducted by Roche Syntex under its IND. Again as later summarized to the FDA by Helsinn, those studies were as follows:

> Study 2330: Intravenous for prevention of highly emetogenic CINV.[10]
>
> Study 2332: Oral for prevention of highly emetogenic CINV.
>
> Study 2500: Intravenous for PONV.
>
> Study 2502: Oral for PONV.

(See DTX-0293-0033.)

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[10] There was another Phase II clinical trial also directed to intravenous use in prevention of highly emetogenic CINV (Study 2120), but it was discontinued due to poor patient enrollment. (See PTX-261.0002.)

The Phase II Study 2330 ("the 2330 study") was named "A dose-ranging, efficacy, safety, and pharmacokinetic study of single intravenous doses of RS-25259 for prevention of nausea and vomiting in chemotherapy-naive cancer patients receiving highly emetogenic chemotherapy." (DTX-0227-0005.) That study started in May 1994. (See id.) The Final Report of that study was dated July 1995, and signed on September 25, 1995. (DTX-0227-0005, -0016.)

The Introduction section of the 2330 study Final Report stated in part as follows:

> Cancer chemotherapy may be associated with a high incidence of nausea and vomiting, particularly when certain agents such as cisplatin are used. Nausea and vomiting may be triggered by the release of . . . (5-HT) via a cascade of neuronal activation involving both the gastrointestinal tract and the central nervous system. Emesis may be seen acutely (within 24 hours of the start of chemotherapy), after a delay (beginning 24–48 hours after chemotherapy), or even in anticipation of chemotherapy . . . . With repeat courses of chemotherapy, emesis becomes progressively more difficult to control, although adequate control in the first chemotherapy cycle is more likely to be associated with control of acute emesis in subsequent cycles. Therefore, antiemetic efficacy is generally studied first in chemotherapy-naive patients.
>
> In the United States, currently available antiemetic therapies include either single-drug or combination therapy with phenothiazines, steroids, or metoclopramide (a mixed 5-HT3 and dopaminergic-receptor antagonist), or most recently ondansetron (a 5-HT3 receptor antagonist). All of these therapies must be

> given as multiple-dose regimens because of their short half-lives, and none is completely effective in preventing the severe nausea and vomiting associated with cancer chemotherapy.
>
> RS-25259-197 (hereafter referred to as RS-25259) is a novel, potent, and selective 5-HT3 receptor antagonist. In animal models of chemotherapy-induced emesis, RS-25259 completely inhibits emesis in up to 100% of animals given high-dose cisplatin. In humans, the mean half-life of the drug is approximately 40 hours, whether administered intravenously or orally. Given the high affinity for the receptor, excellent efficacy in animals, and long half-life in humans, a single dose of RS-25259 may control acute chemotherapy-induced emesis.
>
> This was the first randomized, double-blind trial of intravenously administered RS-25259 in chemotherapy-naive cancer patients.

(DTX-0227-0017 to -0018 (footnotes omitted).)

The stated objectives of the 2330 study included: "(1) [to] determine the dose-response relationship among single IV doses of RS-25259 over the dose range 1-90 μpg/kg . . . . " (Id. at -0014.) The Final Report of the 2330 study concluded as follows:

> RS-25259, administered as a single intravenous bolus injection of 3, 10, 30, or 90 μpg/kg 30 minutes prior to high-dose cisplatin chemotherapy, was effective in suppressing chemotherapy-induced emesis for 24 hours. All four doses were approximately equally effective as compared with the combined results from a cohort of 0.3 and 1 μpg/kg.

. . . .

> Based on the results of this study, a dose of 3 μg/kg or 10 μg/kg RS-25259 might be appropriate for further development.

(Id. at -0015 to -0016.)

The 2330 study Final Report also noted the following pharmacokinetic observations: "The plasma half-life was exceptionally long for this class of compound, and a few patients demonstrated very long half-lives compared with the other patients." (DTX-0227-0016.)

There were, however, significant questions about effective dosage levels remaining at the end of the 2330 study, as described in that same 2330 study Final Report. The Discussion section of the Report stated as follows:

> A statistically supported dose-response relationship for efficacy . . . between the lowest dose level of RS-25259 and each subsequent higher dose level was not observed in this study. The statistical analyses, defined prior to study start, were essentially confounded by the relatively high response rate observed among patients who received the lowest dose of RS-25259, namely 0.3–1 μg/kg. This was not expected and the reasons for this response are unclear. One could perhaps speculate and perform additional statistical tests, but that would be beyond the scope of the preplanned analysis.
>
> Nevertheless, based on published data that shows that almost all patients who receive high doses of cisplatin experience nausea and vomiting, the results of this study suggest that RS-25259 is an effective agent.

> Based on clinical observation, a single intravenous bolus injection of 3, 10, 30 and 90 μg/kg RS-25259 30 minutes prior to cisplatin chemotherapy was effective in suppressing chemotherapy-induced emesis for 12 to 24 hours .... Although no placebo control was incorporated into the design of this study, there appeared to be a step up in efficacy from the combined 0.3–1 μg/kg dose group to doses of 3 μg/kg and more. The four highest doses were approximately equally effective when compared with the results from the combined 0.3–1 μg/kg cohort, suggesting a plateau in the dose response for RS-25259 when administered at a dose greater than 3 μ g/kg. RS-25259 was well tolerated in this study. No safety issues related to RS-25259 were apparent.

(Id. at -0055.)

When Helsinn later approached the FDA for permission to commence Phase III clinical trials, these facts and the underlying data reflected in the 2330 study led the FDA to conclude that the 2330 study itself did not provide any reliable dose response data, except possibly at the much higher 30 microgram per kilogram level. See Section I.C.5.

The dosages measured in the Phase II 2330 study were expressed in micrograms of palonosetron per kilogram of patient body weight, i.e., "weight-based" measurements, as stated in the above-quoted passage. At trial there was no dispute that the "3 microgram per kilogram" figure, expressed in that Report, is approximately the numerical equivalent of the 0.25 milligram dose actually claimed in the '219 patent for treatment of CINV. (See, e.g., dkt. 322 at 121.) In the Phase III trials for CINV treatment, described below, Helsinn chose to study

"fixed-dose" amounts of 0.25 mg dose and 0.75 mg dose. (See id. at 132.) The 0.75 milligram dose likewise corresponds to the "10 microgram per kilogram" figure in the 2330 study. (See PTX-182.0009 to .0010.)[11]

The 2330 study was a well-designed study in that it was randomized, double-blind, and multi-center. (See DTX-0227-0014.) On the other hand, as was appropriate for such a Phase II study, it involved only a small number of patients (161 patients, of which 18 were excluded from the efficacy results for valid reasons), and the total number of patients receiving each dose level ranged between only 24 and 46. (Id.)

There was also no formulation data at all in the 2330 study, on stability or any other properties, because the palonosetron was simply diluted in saline solution and buffered for injection. (Id. at -0015; dkt. 324 at 86- 89.) In that form, it was not stable at room temperature and required refrigeration and resupply in the course of the study. (Dkt. 322 at 102.) In fact, although the Roche Syn-

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[11] The following table of conversion equivalents from weight-based dose units to fixed-dose units is contained in the Helsinn Phase III data, and was not disputed at trial:

Weight-based dose groups	Fixed dose groups
0.3 μg/kg – 1 μg/kg	<0.1 mg
3 μg/kg	0.25 mg
10 μg/kg	0.75 mg
30 μg/kg	2 mg
90 μg/kg	6 mg

(PTX-182.0010.)

tex formulation books contained some research on possible formulations, that work had not progressed to the actual making of any formulations, complete with excipients, that could have been used for Phase III clinical studies. (Id. at 103–04.)

By 1997, as described below, Roche had discontinued work on the Roche Syntex palonosetron project, deciding not to proceed with it after completion of the Phase II studies. (Id.)[12] At that time, Roche made Helsinn aware that Roche was interested in selling a license on the rights to palonosetron and the existing development research. (Id. at 80.) After a due diligence period under confidentiality restrictions, Helsinn did enter into that license agreement with Roche in early 1998, and began its work on further development of palonosetron into a pharmaceutical product. (Id. at 31, 49.)

3. Helsinn license from Roche

Plaintiff Helsinn Healthcare S.A. ("Helsinn" or "HHC") is a family-owned and family-run Swiss company with headquarters in Lugano, Switzerland. (Dkt. 320 at 108; dkt. 322 at 76–77.) The Roche pharmaceutical organization is a large corporate entity that also has a headquarters in Switzerland. (Dkt. 322 at 86.) In the 1997–1998

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[12] The Syntex scientists who had developed the palonosetron hydrochloride compound and taken it through the Phase II stage of development did publish a few materials in the 1995–1998 time period. Those publications were later listed as prior art references in the patents-in-suit. (See, e.g., '724 patent, page 1, listing references by R.M. Eglen, J. Chelly, and J. Tang.) Those references, and a 2001 set of abstracts by Helsinn researcher G. Piraccini (also identified as prior art in those patents), are particularly relevant to the obviousness issues in this case, as discussed in the testimony of the parties' expert witnesses on those issues.

time frame, Roche and Helsinn would periodically communicate about potential licensing arrangements. (Id.) That is how Helsinn was informed that Roche had decided to terminate its palonosetron development project at the conclusion of the Phase II studies and was interested in licensing out the rights to the project. (Id. at 86–87.).

The Helsinn organization at that time had been managed by the founder, Gabriele Braglia, who was transitioning the leadership of the company to his sons, Enrico and Riccardo Braglia. (Id. at 86.) Dr. Giorgio Calderari is a Ph.D. chemist and current group general manager and chief operating officer at Helsinn in Lugano. (Dkt. 320 at 106.) He is a named inventor in the four patents-in-suit. (Id.) He testified at length at trial, called as a witness by both sides. (Dkt. 320 at 105–225; dkt. 322 at 9–175.)

Dr. Calderari recalled that when he joined the organization in 1985, it was a small company with a staff of about 20 employees at Lugano and another 15 employees at its chemical plant in Biasca, Switzerland. (Dkt. 322 at 77–78.) In the 1997–1998 time period, before Helsinn began its development of palonosetron, its organization had grown to approximately 200–250 employees. (Id. at 78.) Its operations were located as before in Lugano and Biasca, as well as in a finished drug product plant in Ireland at a subsidiary, Helsinn Birex Pharmaceuticals Ltd. ("Helsinn Birex"). (Id. at 77; dkt. 320 at 202.) At that time, its major product was an anti-inflammatory drug that was sold in Europe and South America, but sales were declining because it was going off patent, and Helsinn had no products in the United States pharmaceutical market. (Dkt. 322 at 77, 87.)

The business plan of Helsinn, at the time it licensed palonosetron from Roche in 1998, was described by Dr.

Calderari as a "business-to-business" model. (Dkt. 320 at 110–11.) Helsinn would take licenses from others who had developed new chemical entities and continue that development process, while simultaneously seeking partners for eventual worldwide distribution. (Id.) In other words, it was looking to in-license drug development projects and try to take them through to the marketing and distribution stage with others. (Id.) Helsinn was not a drug discovery company at that time, and it did not have its own sales force. (Id. at 111.) Nor did it have its own formulation research and development laboratories. (Dkt. 330 at 7–8.) It would obtain those services from contract research organizations ("CROs") and contract manufacturing organizations ("CMOs"). (Id. at 7.)

When Helsinn was considering the prospect of acquiring the palonosetron development rights from Roche, it had full access to Roche Syntex's laboratory and Phase II documentation, and it was able to speak with the scientists there. (Dkt. 320 at 114–15; dkt. 322 at 81.) Dr. Calderari was part of the team at Helsinn that was responsible for evaluating that opportunity. (Dkt. 320 at 114.) He testified that the Helsinn team's view of the project, after making its due diligence review, was that from a scientific standpoint it could enable Helsinn to enter a new field of research, and it could be an opportunity for Helsinn to enter the U.S. market, "but we were also aware that there was some risk that we would have to overcome in order to arrive at a successful product." (Dkt. 322 at 87.)

The class of molecules known as 5-HT3 receptor antagonists, commonly called setrons, had already been developed into pharmaceutical products, although none of the setron molecules covered by Roche Syntex's '333 patent had yet been developed to that point. (Id. at 80.) At

that time in early 1998, there were already three setron products on the market in the U.S., namely ondansetron, dolasetron, and granisetron. (See id. at 89.) They were sold by major companies including GlaxoSmithKline and Sanofi-Aventis.[13] (Id. at 92.) Those products contained different setron compounds, but Helsinn understood that they were considered interchangeable. (Id. at 91.)

The palonosetron project documents reviewed by Helsinn showed that Roche itself, in view of Syntex's Phase II testing, did not see any particular efficacy advantages of palonosetron compared to the existing setron products, nor did it see market potential. (Id. at 81–82.) So even if Helsinn were to succeed in developing a commercial formulation and obtaining FDA approval after Phase III clinical trials, the palonosetron product would be a fourth setron in the same class, a so-called "me too" compound. (Id. at 82.) It would likely earn only modest sales, according to Roche's projections. (Id. at 83.) Furthermore, the earliest of those setrons, ondansetron, was losing its patent protection in 2005. (Id. at 144.) Roche charged Helsinn a relatively modest sum, $10 million, for the license rights to palonosetron, with further royalties due only if and when a product was approved and launched. (Id. at 84.)

Helsinn was also aware, from scientific publications, that at that time many companies including Roche were developing or were looking to another class of antiemetic products called NK-1, referring to neurokinin receptor

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[13] Zofran®, or ondansetron, was approved by the FDA for the treatment of CINV in January 1991. (Dkt. 330 at 155.) Kytril®, or granisetron, was approved by the FDA for treatment of CINV in December 1993. (Id. at 156.) Anzemet®, or dolasetron, was approved by the FDA for the treatment of CINV in September 1997. (Id.)

antagonists. (See id. at 85.) In fact, at a later time, in or about 2005, Roche licensed to Helsinn an NK-1 compound named netupitant, and Helsinn took it from the end of Phase I trials through FDA approval and its launch in the U.S. in 2014. (Id. at 86). Also Roche, even while discontinuing its palonosetron project and licensing it to Helsinn, and while pursuing development of new NK-1 compounds, actually purchased the rights to the patented 5-HT3 product granisetron some years after 1998, paying over $1 billion for that deal as reported in the press. (Id. at 84.)

Aside from predicted poor marketing prospects for the palonosetron project, there were also technical problems confronting Helsinn as it considered whether to in-license the project. (Dkt. 320 at 124–25.) Helsinn studied Roche Syntex's efficacy records at the end of Phase II, including the results of the Phase II study 2330, which was for treatment of CINV. (Dkt. 320 at 31–32.) In their internal records at the end of Phase II, the Syntex scientists themselves had recommended that for a CINV indication (as contrasted with a PONV indication, which would typically be at a lower dosage), the minimum dose to be selected for Phase III trials should be 1.0 milligram, not the equivalent of 0.25 or 0.75 milligram doses suggested in the 2330 study conclusions. (Dkt. 322 at 111–12.)[14]

The Syntex scientists had also recommended (but not prepared or tested) a formula concentration level of 0.4 milligrams of palonosetron per milliliter of solution for the CINV Phase III trials. (Dkt. 322 at 111.) However, the

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[14] Helsinn's PONV clinical expert, Dr. Keith Candiotti, testified that CINV dosage of setrons was generally higher than PONV dosage. (Dkt. 331 at 85.) Teva's clinical expert, Dr. David Frame, testified to the same effect. (Dkt. 328 at 121–22.)

Syntex formulation studies indicated that "[t]he higher the drug concentration in the solution, the less stable it becomes." (Id. at 113.) So stability itself was an issue, but so were dosage and concentration. (Id.) As Dr. Calderari summarized the situation:

> The problem is that from a chemical point of view, you wish to have the lowest possible concentration . . . because this increased the probability of having a stable solution. On the other hand, for showing efficacy, you have to have a dose or a concentration which is enough high [sic] so that the product will be at the end efficacious in the patient.

(Id. at 114–15.)

Keeping in mind all of those considerations, Helsinn did make the decision to proceed with the palonosetron project, entering into the license with Roche in early 1998. (See id. at 49.) As part of that deal, ownership of all the remaining developmental batches of the palonosetron API was transferred to Helsinn. (Id. at 104.) Roche specified that those supplies of API could be used only for developmental purposes, including Phase III clinical trials; that API could not be used for a commercial product. Helsinn complied with that restriction. (Id. at 104–05.)

Helsinn began its work under the license agreement with Roche by building a "project team." (Dkt. 320 at 109.) Dr. Calderari was in charge of the "chemistry manufacturing and control" ("CMC") part. (Id. at 109–10.) He explained that involved "developing the API . . . drug processes [and] quality control, up to having everything ready for the release and collecting all the necessary chemical stability data for filing a New Drug Application." (Id. at 110.) Dr. Calderari was assisted in those functions

by Dr. Daniele Bonadeo, whose degree was in chemistry and pharmacy and who also became a named inventor on the patents-in-suit. (Dkt. 330 at 5-6.)[15]

The dose selection and clinical studies for Helsinn's project were supervised by Dr. Alberto Macciocchi, a medical doctor who was also a Helsinn employee, in consultation with Dr. Calderari and his CMC group. (Dkt. 322 at 48, 119.)[16] There were also chemical people at Helsinn's own API manufacturing plant, and regulatory staff, as part of the Helsinn project team. (Dkt. 330 at 9.) In addition, Helsinn engaged a former Syntex scientist, Thomas Malefyt (another named inventor on the four patents-in-suit), who had been the CMC leader of the Roche Syntex palonosetron project team. (Dkt. 322 at 99–100.) He rendered a consulting report addressing the related issues of stability, dose selection, and concentration in designing the Phase III trials. (Id. at 115–16.) As Dr. Bonadeo testified, "the aim . . . was to have an NDA for CINV use of palonosetron." (Dkt. 330 at 9.)

There were substantial communications between the Helsinn project team and the former Syntex researchers, as well as other specialist consultants engaged by Helsinn, during the period starting in 1998 when Helsinn licensed the palonosetron project from Roche Syntex.

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[15] Dr. Bonadeo was deposed in this action, and portions of his testimony were placed in evidence at trial. (Dkt. 330 at 5–37.)

[16] Dr. Macciocchi passed away in approximately the mid-2000's. (Dkt. 322 at 48.) However, he was still functioning as project supervisor in the clinical area when Helsinn received the first of the Phase III preliminary results and forwarded them to the FDA in early 2002. (Id. at 59–65.) He continued in that same position to the end of Phase III and beyond, and he signed all of the Phase III final Clinical Study Reports. (DTX-0288-0004; DTX-0289-0003; DTX-0290-0003.)

Much of that work involved studying the Syntex Phase II clinical data and considering what doses and concentrations of palonosetron to recommend to the FDA for Phase III clinical trials.

Helsinn confidential records in that period include minutes of a week-long meeting in Palo Alto, California from July 20 to July 24, 1998 ("1998 Helsinn Clinical Meeting Minutes"). The persons attending that meeting included Dr. Macciocchi and Dr. Calderari from Helsinn; former Syntex researchers including Mr. Malefyt; Dr. David Gandara from University of California Davis, a prominent medical oncologist (see dkt. 324 at 45–46); and other doctors and scientists.

The summary of that meeting, as reported in the Minutes, stated in part:

> **Overview**
>
> . . . . After much consideration, and pending further statistical analyses of the phase 2 data, the following drug doses and concentrations are proposed for the CINV . . . trials.
>
> | Dose | mg/ml |
> |---|---|
> | 0.25 mg | 0.05 |
> | 0.75 mg | 0.15 |
> | 2.0 mg | 0.4 |
>
> . . . .
>
> **Planned data analyses**
>
> A further analysis of the phase 2 data is important, including

- by sex,
- μg/kg converted to per mg dosing,
- splitting the 0.3 and 1 pg/kg doses, and
- conducting a pk/pd analysis.

2. Safety should be reviewed by mg dosing.

3. Phase 1 volunteer data (pk) should be compared with phase 2 patient pk data.

4. The long half-life should be investigated on a per patient basis.

5. Phase 2 days 2-5 should be analyzed further (and evaluate in comparison with ondansetron days 2-5).

(DTX-0015-0008 to -0009.)[17]

4. The Oread agreements

Helsinn was aware that it would need manufacturing and testing capabilities in order to proceed to Phase III trials. (Dkt. 322 at 123–24.) The immediate need was to be able to create sufficient quantities of an actual formulated composition for use in the Phase III clinical studies. (Id.) That formulation would contain the palonosetron API batch material Helsinn had purchased from Roche, if the

[17] In the detailed contents of the 1998 Helsinn Clinical Meeting Minutes, it was noted that "Gandara recommended that, despite the unusual result in 2332 [the Phase II study on oral palonosetron for highly emetogenic CINV], 3 μg/kg was most likely the correct dose for CINV." (DTX-0015-0012 (bracketed text added).)

FDA agreed. (Id. at 123.) It would also contain the excipients that Helsinn would select for inclusion in the intravenous formulation that would be administered to the Phase III subject patients.[18] That Phase III intravenous formulation would be subject to FDA supervision as to manufacturing quality. (Id. at 135.) It would also have to be tested for properties including quality and stability, with those results reported to the FDA before and during the Phase III process. (Id. at 134–35.)

Looking beyond the Phase III trial period, if Phase III was successful and Helsinn decided to try to market a product based on that IND in the U.S. market, Helsinn would have to file a New Drug Application. One of the many requirements of Helsinn's NDA filing would be to document how and where the applied-for product or products would be manufactured and packaged for commercial distribution. (Id. at 135–36.) In connection with any such NDA, sample batches of commercial product would have to be submitted to the FDA, with full manufacturing documentation. Helsinn would need to arrange for the manufacture of new palonosetron API supplies for commercialization because as noted above, Helsinn's license from Roche did not permit the Syntex-made API supplies to be used in any commercial products.

Even before the license between Roche and Helsinn was finalized in early 1998, Helsinn had entered into a Confidential Disclosure Agreement, dated November 25, 1997, with a company named Oread, Inc. ("Oread") for the purpose of exploring a development and manufacturing

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[18] According to Dr. Calderari, before Helsinn licensed the palonosetron development project from Roche, Syntex had made the determination to pursue an intravenous formulation for purposes of the Phase III trials. (Dkt. 322 at 23–24.)

relationship ("Oread Confidentiality Agreement"). (See DTX-0391-0002.) Oread was a company located in California, on the same campus as Syntex. (Dkt. 320 at 159.) It was an entirely separate company, not related to Helsinn. (See id.) Some of the personnel at Oread had come from Syntex, including Kathleen M. Lee, who later was named as one of the inventors on the patents-in-suit. (See DTX-1023-0001; dkt. 322 at 170–71.)

On July 13, 1998, Helsinn and Oread signed a contract entitled "Development and Manufacturing Agreement" ("Oread Development Agreement"). (DTX-0391-0001, et seq.) That Development Agreement expressly incorporated the confidentiality restrictions contained the Oread Confidentiality Agreement. (Id. at -0002.)

There were a number of functions that Oread contracted to perform under that Development Agreement, as generally described in its Exhibit A, Part I, Statement of Work, and as explained in the testimony of Dr. Calderari. (Id. at -0009; dkt. 320 at 172–176; dkt. 322 at 122–30.) Those functions included analytical and formulation development work, as well as taking the Syntex-manufactured palonosetron API owned by Helsinn (located in Boulder, Colorado, see dkt. 320 at 195), and manufacturing "developmental batches" of product formulation. (Dkt. 320 at 176.) That formulation would be used both for Phase III stability and quality testing, and for administration to patients in the Phase III clinical trials. (Dkt. 322 at 134–35.) The Oread Development Agreement also specified that Oread would perform the stability testing on the developmental formulation batches. (DTX-0391-0009.)

The Oread Development Agreement stated that Helsinn would provide sufficient palonosetron API to Oread for the Phase III clinical formulation manufacturing; and

the Oread scope of work expressly did not include any API development and manufacture. (Id.) In other words, as Dr. Calderari explained, "we would give our API to them, and they would use them to prepare the . . . formulation batches, for then giving us back to prepare to investigate in the Phase III clinical trials." (Dkt. 322 at 123–24.) He also testified that although Helsinn and Oread had discussions about Oread's potential capacity "in helping us in the future manufacturing commercial batches," no such agreement was ever reached. (Id. at 125; see also dkt. 320 at 160–61.)

Helsinn and Oread commenced working together under the Oread Development Agreement dated July 13, 1998, and continued those activities until Oread suddenly went out of business in mid-2000, during the Phase III trials, leaving Helsinn to find a substitute contractor. (Dkt. 320 at 169–70.) The functions that Oread did perform under contract during that period, for which it was paid by Helsinn, are summarized below.

5. FDA meeting March 10, 1999

Armed with all the existing Roche Syntex project information and its evaluations of that information, Helsinn notified the FDA that the Roche Syntex IND 39,797 had been transferred to Helsinn. In a December 23, 1998 submission to the FDA, Helsinn "described plans to develop palonosetron hydrochloride injection for the prophylaxis of . . . (CINV), . . . summarized palonosetron's clinical development to date and requested an End of Phase II meeting." (PTX-261.0002.) The stated purpose of the meeting was "to get the Division's input on (1) the planned phase III development program, (2) . . . the adequacy of the technology transfer program of drug substance from

the Syntex Boulder facility to the Helsinn Switzerland facility, and (3) . . . the sufficiency of the preclinical data to support a future NDA." (Id.)

The "End of Phase II" meeting was conducted at the FDA on March 10, 1999, and official minutes of the meeting were prepared by the FDA and distributed to the participants. (Id. at .0001) The meeting was attended by numerous listed FDA representatives, representatives of Helsinn including Dr. Calderari and Dr. Macciocchi, and consultants for Helsinn who were also named in the minutes.[19] In preparation for that meeting, Helsinn had provided the FDA with a "briefing package," and listed questions on which it sought FDA input. (Id. at 261.0002–.0003.)

Those listed Helsinn questions and the FDA answers, as set forth in the minutes, referred to two proposed Phase III clinical trials named PALO-99-03 and PALO-99-04 that would assess CINV in "moderately emetogenic" chemotherapy. They also referred to the fact that for all Phase III trials, Helsinn's proposed doses were 3 and 10 micrograms per kilogram (i.e., equivalent to 0.25 and 0.75 mg, see n. 11 supra). (Id. at 261.0007–.0008.) There were also proposed trials named PALO-99-

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[19] Two of the consultants listed in the FDA March 10, 1999 meeting minutes were a representative of August Consulting, and a representative of Oread, Inc. (PTX-261.0001.) As Dr. Calderari testified, Helsinn as a foreign corporation was required to communicate and file documents with FDA through an FDA-recognized U.S. representative, and that was the function of August Consulting. (See dkt. 320 at 139.) The Oread representative was present pursuant to the July 1998 Development and Manufacturing Agreement between Helsinn and Oread that Dr. Calderari described in his testimony. See Section I.C.4.

05 and PALO-99-06 discussed in the minutes, as more particularly explained below.

The FDA in that meeting, as reflected in the minutes, was adamant that the Phase II study 2330, although named a "dose-ranging, efficacy . . . study," had not produced sufficient data to establish what the minimum effective dose of palonosetron in an intravenous pharmaceutical formulation for CINV would be. In the Background section of the minutes, discussing the 2330 study, the FDA stated:

> **Study 2330** was a single-dose, double-blind, parallel, multi-center dose-ranging study in which 161 patients (129 males, 32 females) were randomized to 0.3, 1, 3, 10, 30 or 90 mcg/kg of palonosetron. According to the firm, the objective was to determine dose-response over a wide range of palonosetron doses, using the low-dose levels of palonosetron for control. The primary efficacy measure was the proportion of patients with no emetic episodes and no rescue medication. When compared to the lowest doses (0.3 and 1 mcg/kg) only the 30 mcg/kg dose was statistically significant; a significant dose response trend was not evident.

(PTX-261.0002.)

This FDA minutes statement was referring to the fact that as reported in the 2330 study, at the 3 and 10 mcg/kg levels (equivalent to the 0.25 mg and 0.75 mg dosages that Helsinn ultimately proposed and selected for its Phase III trials), there was no statistical significance to any of the efficacy data in that study. Indeed, according to the FDA at that meeting, the only statistically significant dose level indicating efficacy in the 2330 study for CINV (using a

highly emetogenic chemotherapy agent) was 30 mcg/kg, or ten times higher than the 3 mcg/kg dose.

Additional statements in the FDA minutes of the March 10, 1999 meeting emphasized that determining the dose-related efficacy of the proposed palonosetron pharmaceutical formulations would have to abide the results of the Phase III trials. Here are some of those question and answer exchanges:

Clinical – Question 5

Are the two trials presented in moderate dose CINV [referring to PALO-99-03 and PALO-99-04], with repeat cycle and pediatric data, considered sufficient to support the label claim, "Prevention of nausea and vomiting associated with initial and repeat courses of emetic cancer chemotherapy"?

- **This question is premature. The program appears adequate, however, all regulatory decisions, including any labeling claims, will be data driven. (Division representatives also noted that a dose response was not shown in Phase II Study 2330, and therefore it is questionable whether the appropriate palonosetron dose has been identified.)**

Clinical – Question 6

Is [Phase II study] 2330 sufficient to support the label claim "Including high dose cisplatin"? Should a historical control analysis be conducted?

Note: In the question above, the firm appears to have written "high dose cisplatin" when "highly

> **emetogenic chemotherapy" is what was intended . . . .**
>
> - **Due to the lack of a dose response in this study, these data are inadequate to serve as pivotal efficacy support (although they may be useful as supportive data).**
>
> **(After discussion with the firm, it was agreed that the results of Study 2330 versus a historical control, along with another study in which two doses of palonosetron are compared to ondansetron, then validated by comparison to a historical control could be used to support a claim for palonosetron in the prevention of nausea and vomiting due to highly emetogenic chemotherapy. Note: Any regulatory decisions will be data driven.)**

(PTX-261.0005–.0006 (emphasis in original; bracketed text added).)[20]

Similarly, in commenting on the "protocol summaries" Helsinn had submitted before the meeting, with respect to proposed PALO-99-03 and PALO-99-04 trials involving

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[20] As referred to in this quoted text, and as seen in the later-submitted FDA filings, Helsinn was permitted to proceed with just one full-scale Phase III study for the highly emetogenic CINV ("HEC") efficacy, which was PALO-99-05. Helsinn was permitted to submit the re-analyzed results of study 2330, designated PALO-00-01, as the "supportive data" accompanying the PALO-99-05 HEC clinical trial. (See dkt. 322 at 108–26, 134.) Therefore, Helsinn was not required to conduct what would have been PALO-99-06, a second full-scale Phase III clinical trial for HEC efficacy. See n. 22 infra.

moderately emetogenic chemotherapy, the FDA advised Helsinn:

> **Efficacy data for Study 2330 show that results for the 0.3-1 mcg/kg doses did not differ significantly from the proposed Phase III doses (3 and 10 mcg/kg). Consider including the lower dose as an arm in the Phase III study.**

(Id. at .0008.)

The minutes of the March 10, 1999 FDA meeting also addressed, among other topics, the manufacturing of future commercial batches. The FDA had been made aware that Helsinn proposed to use the Syntex-manufactured palonosetron API in making the pharmaceutical formulations to be used in the Phase III trials, and the FDA expressed concern that for commercialization, the age of that API substance would be problematical. Helsinn replied that they did not plan to use any of that Syntex-made API in manufacturing the commercial batches. The FDA accepted that representation, but made it clear that it would require full disclosure of the planned commercial manufacturing arrangements, as well as commercial product stability data, before it would consider approving a New Drug Application for commercialization of any such product. (See id.) That portion of the minutes stated:

> - **We note your plan to use drug substance manufactured by Syntex (date of manufacture: 1995) for your Phase III drug product. The age of that drug substance is a potential problem.**
>
> **(Note: In response to this comment, the sponsor's representatives indicated that they plan to change**

the drug substance manufacturer prior to submission of an NDA; Helsinn-manufactured drug substance will be incorporated into the drug product planned for commercial use. The Division's chemistry representative indicated that the information to support this change should be presented clearly and completely in the NDA. He said the Helsinn drug substance manufacturing facility(ies) should be prepared to host an inspection at the time of NDA submission. He also said that three batches of drug product manufactured with Helsinn drug substance should be put on stability; at least one of those batches should be commercial scale.)

(Id. at .0003.)

Dr. Calderari testified that the Helsinn development team continued to debate internally the questions of what dosage and concentration level or levels to select for the Phase III protocols during this time period. The Helsinn group at that time recognized the fact that the Syntex scientists, at the end of their Phase II work, had recommended a single 1.0 milligram dose for Phase III CINV testing. They were also acutely aware that the FDA said the Phase II 2330 study did not contain reliable dose-related efficacy data. On the dosage issue, when asked how Helsinn ultimately decided to take the two doses that it did select into the Phase III trials, he stated:

> It was . . . a big debate. I mean, generally speaking, you tend to run Phase III only with one dose, but as we have seen . . . , the FDA was concerned about not having shown this dose efficacy relationship, so our scientists suggested that we should run the Phase III

> with multiple doses, and I recall that we had a long discussion because Dr. Macciocchi wanted even to have a third dose, much higher. Then at the end, we came to a compromise to use these two doses, and this what then was proposed to the FDA in the end of Phase II [March 10, 1999] meeting.

(Dkt. 322 at 119 (bracketed text added).)[21]

Dr. Calderari also explained that the stability issue was also in the forefront of Helsinn's considerations at that time. Although Syntex had recommended a formulation containing 0.4 milligrams of palonosetron per milliliter of solution for a CINV product, there was a concern about stability of the product at that concentration. The Syntex internal documents had identified that "the higher the drug concentration in the solution, the less stable it becomes." (Dkt. 322 at 113, referring to DTX-0254 at 27.) The Syntex inventor Dr. Malefyt, in his September 14, 1998 consulting report to Helsinn, had similarly advised:

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[21] The March 10, 1999 FDA meeting minutes indicate that at that time, Helsinn had submitted only "protocol summaries" rather than completed proposed testing protocols, and that the doses being proposed at that meeting were expressed in micrograms per kilogram of patient body weight, specifically 3 and 10 mcg/kg. (See PTX-261.0007, .0008.) As discussed below in this Section, when Helsinn submitted its formal proposed Phase III protocols in April 2000, it had decided to simplify the protocols by specifying dosage in fixed-dose milligrams, rather than in relative micrograms per kilograms of patient weight, thus proposing 0.25 and 0.75 mg doses for Phase III. Throughout the trial evidence, including testimony by the parties' experts, those two different measurement forms were discussed in their equivalent values. Thus the parties recognized, for example, that 3 mcg/kg is equivalent to 0.25 mg. (See, e.g., dkt. 322 at 121.)

> The [P]hase [I and II] IV product required refrigeration. Stability is inversely related to [palonosetron] concentration apparently in both solid and liquid forms. If doses around 10 mcg/kg are required to obtain efficacy for CINV and PONV (both IV or oral liquid capsules), it will be challenging to formulate an IV and oral dosage form that provides sufficient mcg dosage to provide efficacy and also be sufficiently stable.

(PTX-245.0005 (bracketed text added).)

Dr. Calderari summed up the problem facing Helsinn in trying to achieve a balance between efficacy and stability in creating a Phase III formulation as follows:

> So at the end, this is the dilemma we lived from the – .... So the dilemma was, me, as a chemist, I wanted – or my team wanted – a diluted as much solution, so less concentration (to make sure that at the end we would have had a product that would have been shelf stable), but of course the clinician wanted to use a dosage that was sufficient[ly] high to meet the requirement to treat emesis.

(Dkt. 322 at 117–18 (bracketed text added).)

6. Phase III protocol

Ultimately, Helsinn decided that to balance the documented concerns about efficacy and stability, it would take two different dosages and concentration levels into its Phase III trials for CINV. (See id. at 119.) On April 7, 2000, it submitted to the FDA a set of "safety and efficacy protocols" for Phase III clinical testing designated as follows:

- PALO-99-03 entitled, "A Double Blind Clinical Study to Compare Single IV Doses of Palonosetron, 0.25 or 0.75 mg and Ondansetron, 32 mg IV, in the Prevention of Moderately Emetogenic Chemotherapy-Induced Nausea and Vomiting"

- PALO-99-04 entitled, "A Double Blind Clinical Study to Compare Single IV Doses of Palonosetron, 0.25 or 0.75 mg and Dolasetron, 100 mg IV, in the Prevention of Moderately Emetogenic Chemotherapy-Induced Nausea and Vomiting"

- PALO-99-05, entitled "A Double Blind Clinical Study to Compare Single IV doses of Palonosetron, 0.25 or 0.75 mg and Ondansetron, 32 mg IV, in the Prevention of Highly Emetogenic Chemotherapy-Induced Nausea and Vomiting"

(DTX-0293-0001.)[22]

As shown in these protocol titles, all three protocols specified using both 0.25 and 0.75 mg doses of palonosetron. The 99-03 and 99-04 studies were directed to moderately emetic CINV ("MEC"), and the 99-05 study was directed to highly emetogenic CINV ("HEC"). The protocols specified that the selected concentrations of palonosetron API in the formulations for all three studies would be 0.05 mg/ml for the 0.25 mg dosage and 0.15 mg/ml for the 0.75 mg dosage. (See dkt. 322 at 108.) These concentrations were sharply lower than the 0.4 mg/ml that Syntex had recommended for the CINV formula. (See id.) The

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[22] No PALO-99-06 study was needed, based upon the fact that the FDA allowed Helsinn to re-analyze the results of Phase II study 2330, designate that report as PALO-00-01, and submit it as support for the PALO-99-05 Phase III results. (See n. 20 supra; PTX-182.)

low concentrations were reflective of the goal, as described by Dr. Calderari, to promote stability by decreasing the concentration of palonosetron in the pharmaceutical formulation. (See id. at 113.)

Dr. Calderari was asked why Helsinn chose to bring two doses into each of those Phase III CINV trials, both of which were lower than the 1.0 mg dose for CINV that had been recommended by Syntex. (See id. at 120.) He said, "this was this compromise between increasing the chances of having a stable product from one side, and increasing the chances to have an efficacious product on the other side." (Id.) He explained that the risk that Helsinn took in selecting those relatively low doses for CINV was "that at the end, we would end up with a product that was not efficacious enough." (Id.)

Dr. Calderari testified, under questioning by counsel for Helsinn, that Helsinn did not know whether these lower doses would work for CINV efficacy, prior to receiving the results of the Phase III trials. He stated the reason was "[b]ecause it was not tested before, and during the Phase III trial, you have absolutely no idea how the clinical trial is going in terms of results." (Id. at 120–21.)

Helsinn itself made an apparently contrary statement, however, in its proposed Protocol No. PALO-99-03, dated November 15, 1999. There, referring to the table of data in the Phase II 2330 study summarizing patients' responses for CINV treatment with doses from 0.3/1 mcg/km to 90 mcg/kg, Helsinn stated, "Data from this study clearly demonstrate that the 3 μg/kg dose of palonosetron is the minimal effective dose in preventing CINV." (DTX-0293-0035.)

Chronologically, that statement was dated in late 1999 and submitted to the FDA in April 2000, despite the FDA's statements to Helsinn in the March 10, 1999 meeting minutes, that "a dose response was not shown in the Phase II Study 2330," and that "only the 30 mcg/kg dose was statistically significant; a significant dose response trend was not evident." (PTX-261.0001, .0005). When queried about it by counsel for Teva, Dr. Calderari testified as follows:

> Q. . . . . The term "minimal effective dose" is particularly important, isn't it?
>
> A. Well, I am not a medical doctor, but this is standard. I mean, if you want to go to a Phase III clinical trials, it's a fact that you have to have shown some efficacy in Phase II. Otherwise, you cannot jump and you will even not get the approval to go to the Phase III. So, yes, the product was showing some efficacy clearly.
>
> Q. Exactly. In real human beings.
>
> A. Yes.
>
> Q. And efficacy meaning it reduced the likelihood of CINV.
>
> A. Right. It was giving enough signal for us to take the risk to continue to the Phase III and getting approval from the FDA to move to the Phase III and show if we were really able to show a real efficacy to get an approval by the FDA, but this is standard. You finish the Phase II. You see a some signal. You go with the agency. You discuss, and then if everything is fine, you move to the next step.

(Dkt. 320 at 142–43.)

His testimony on this point was consistent, however, with the actual statements made by Syntex in the 2330 study Final Report, quoted in full in Section I.C.2, where Syntex reported, **"A statistically supported dose-response relationship for efficacy ... between the lowest dose level of RS-25259 and each subsequent higher dose level was not observed in this study ....** Although no placebo control was incorporated into the design of this study, there **appeared to be** a step up in efficacy from the combined 0.3–1 μg/kg dose group to doses of 3 μg/kg and more .... **Based on the results of this study, a dose of 3 μg/kg or 10 μg/kg might be appropriate for further development."** (DTX-0227-0015, -0016 (emphasis added).) This testimony was also consistent with what the FDA had informed Helsinn at the March 10, 1999 meeting, **"Efficacy data for Study 2330 show that results for the 0.3-1 mcg/kg doses did not differ significantly from the proposed Phase III doses (3 and 10 mcg/kg)."** (PTX-261.0008.) **"[A] dose response was not shown in Phase II Study 2330, and therefore it is questionable whether the appropriate palonosetron dose has been identified."** (Id. at .0005.)

Following the March 10, 1999 FDA meeting, Helsinn continued its preparations to file proposed Phase III protocols with the FDA. The documentary evidence described below shows that as of March 24, 1999, Helsinn had already completed developing, on paper and in actual solution, the 0.05 mg/ml palonosetron concentration, with all measured excipients, that had been described in the Syntex formulation books and was later claimed in the '724, '725, and '424 patents. (The same 0.05 mg/ml palono-

setron concentration (with excipient content) was also reflected in the later-issued '219 patent, as the result of dose 0.25 mg palonosetron in 5 ml solution.) (See dkt. 320 at 175–76.)

Dr. Calderari testified that Example 4 in the written description of all four patents-in-suit is an intravenous formulation description that appeared in the Syntex formulation book. (Id. at 152.) Example 4 is reproduced in the margin.[23]

That same formulation, described in the Syntex research materials, had actually been made up into a bulk batch by Helsinn's contractor, Oread, before March 24, 1999. (See, e.g., DTX-1125-0001 to -0006.) This fact was reflected in statutory declarations with supporting documentation later filed in the USPTO during the prosecution of the patents-in-suit and related patent applications. One such example, under the application that led to issu-

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[23] Formulation I

The following is a representative pharmaceutical formulation containing palonosetron that is useful for intravenous formulations, or other liquid formulations of the drug.

Ingredient	mg/mL
Palonosetron Hydrochloride	0.05*
Mannitol	41.5
EDTA	0.5
Trisodium citrate	3.7
Citric acid	1.56
WFJ [water for injection]	q.s. to 1 ml
Sodium hydroxide solution and/or Hydrochloric acid solution	pH 5.0 + 0.5

*calculated as a free base

('724 patent, col. 7, lines 47–66 (bracketed text added).)

ance of the '724 patent, was a declaration of named inventors Calderari, Bonadeo, Cannella, and Enrico and Riccardo Braglia dated November 21, 2007. (DTX-0004-0001 to -0005; see also DTX-1125, a similar Bonadeo declaration dated Feb. 13, 2007, containing the two-page Exhibit A documents referred to in this series of declarations.)[24] That declaration stated, inter alia, as follows:

> 5) This patent application is based on the discovery of liquid formulations of palonosetron with improved stability.
>
> 6) The formulations can be stored for prolonged periods of time in a variety of conditions without significant degradation or loss of potency, and thus are considered pharmaceutically stable.
>
> 7) The formulations were developed by us at Helsinn in the late 1990s, and were completed sometime before March 24, 1999.
>
> . . . .

[24] During the prosecution of the USPTO applications that led to issuance of the '724, '725, and '424 patents, Helsinn submitted declarations signed by named inventors Dr. Calderari, Daniele Bonadeo, Roberta Cannella, and Enrico and Riccardo Braglia (the names of the latter two Helsinn executives were subsequently deleted as inventors per U.S. inventorship requirements). There were several such applications in the patent family history, and those declarations were similar in content but filed under various patent application numbers. (See generally dkt. 289 (chart: Family Tree of Patents at Issue).) Examples of those declarations are in evidence as DTX-0004, DTX-0287-0413, and DTX-1125.

14) The Example 4 formulation was developed by us sometime before March 24, 1999 and transmitted to a contract manufacturer for Helsinn, Oread Laboratories in Palo Alto California ("Oread") for the production of commercial scale batches of palonosetron hydrochloride.

15) A copy of the master batch record developed by Oread for the formulation is contained in Exhibit A hereto.

16) The master batch record describes the Example 4 formulation . . . .

17) As can be seen, the batch record has an effective date of March 24, 1999, and thus makes clear that we developed the formulation before this date.

18) In fact, we had invented and were in possession of all of the subject matter currently claimed in . . . [the applications for the '724, '725, and '424 patents] as of March 24, 1999, because we had completed stability studies for the Example 4 formulation, and understood the effect that variations in palonosetron concentration, pH, and excipient concentrations would have on the stability of the formulation.

(DTX-0004-0001 to -0003 (bracketed text added).)

Dr. Calderari described that when he took over the role for the development of palonosetron at Helsinn, he had to read a variety of results from Syntex. He said that Syntex's formulation book, describing various formulations including Formulation 4, was "where they describe

their attempt, their experiment to arrive to a formulation that might be suitable for clinical trial and then after for commercialization. But to my surprise, when I made the first due diligence, they had never manufactured that formulation, that they had absolutely no . . . data about the stability of potential formulation to be used in a clinical trial." (Dkt. 320 at 116.) Furthermore, he stated that the Example 4 concentration formulation of 0.05 mg/ml was recommended by Syntex to be used in Phase III clinical trials for PONV efficacy (then called "Formulation 90"). (Id. at 116–17.) On the other hand, Syntex had recommended a Phase III palonosetron concentration formulation of 0.4 mg/ml for CINV efficacy (then called "Formulation 89"). (Dkt. 322 at 111–12.)

Dr. Calderari also testified that as to the written description of the Example 4 formulation, as embodied in the actual developmental formulation batches prepared by Oread, the inventor statement that he and the other inventor declarants signed, that "the formulations . . . were completed sometime before March 24, 1999," was a true statement. (Dkt. 320 at 149.)[25] He stated, "[e]xactly, and this is exactly what we have completed at that time. We have completed the selection of the formulation that we will then go and test for stability and for the clinical trial. This is what we had completed at that time." (Id. at 150–51.) He had the same answer regarding the statement at the end of the inventor declaration, "we had invented and were in possession of all of the subject matter

[25] The other inventor declarants, Dr. Bonadeo, Dr. Cannella, and Dr. Braglia, all testified consistently that the statement made regarding the Example 4 formulation was true at the time that they signed the declaration. (See dkt. 330 at 22–23, 41–42, 66.) None of the inventor declarants sought to add any testimony beyond their prior recollection. (See id.)

currently claimed." (DTX-0004-0003.) In his words, "we [had] completed the specification, the selection of this formulation to then be tested in stability studies and in human beings." (Dkt. 320 at 155.)

Helsinn's decision to proceed to CINV Phase III clinical trials with fixed doses of 0.25 mg and 0.75 mg in 5 ml vials was made following the March 10, 1999 FDA meeting (in which a range of doses was discussed, in the weight-based measurements (mcg/kg) used in the Phase II studies), as reflected in the Phase III protocols subsequently submitted to the FDA. (See, e.g., DTX-0293-0001; dkt. 322 at 132.) Dr. Calderari testified that as part of those dosage selections for Phase III, Helsinn decided on corresponding palonosetron concentrations of 0.05 mg/ml and 0.15 mg/ml, which were both lower than the 0.4 mg/ml concentration that Syntex had recommended for CINV Phase III trials. (Dkt. 322 at 108.)

While Helsinn was preparing to submit its completed Phase III safety and efficacy protocols to the FDA, which occurred on April 7, 2000 as described below, Helsinn was communicating with the FDA regarding stability testing of the development formulation lots that Oread had prepared (in the selected palonosetron doses of 0.25 mg and 0.75 mg and concentrations of 0.05 mg/ml and 0.15 mg/ml). A letter from Helsinn to the FDA dated August 19, 1999 stated: "Six month stability data for development lots indicate that the Phase 3 formulation is expected to remain stable for a minimum of 18 months, when stored at 25 °C and protected from light. We commit to monitor stability of the clinical material and to resupply the drug product as appropriate, to ensure that the clinical material has the identity, quality and purity it purports to have." (DTX-0999-0002.) Dr. Calderari said this was "the formulation

we pick[ed] up and we improved, we optimized, and we ran at Oread, and by the time we made the submission, we have six months' stability data." (Dkt. 322 at 163.)

The formal Phase III safety and efficacy protocols for PALO-99-03 and PALO-9904 (two MEC studies) and PALO-99-05 (one HEC study) were submitted to the FDA by letter dated April 7, 2000, under the existing IND number 39,797. (DTX-0293.) At that time, Oread was still performing its contractual functions in support of the trials. For example, a memo from Oread to Helsinn dated April 10, 2000 described "two phase 3 clinical lots" manufactured by Oread in March and April 1999, containing either 0.05 mg/ml or 0.15 mg/ml palonosetron, in 5 ml glass vials according to the Phase III specifications. It reported chemical and physical stability based on up to 6 months of available data, and "[t]he stability monitoring of these two clinical lots is continuing according to the protocol." (DTX-1027-0038.) Dr. Calderari confirmed that Oread did provide clinical supplies of the formulation that is covered by the patents-in-suit for Helsinn, in preparation for conducting the Phase III trials, and Helsinn paid Oread for those batches. (Dkt. 320 at 179–82.)

The INTRODUCTION section of the formal Protocols for all three Phase III clinical studies, PALO-99-03, PALO-99-04, and PALO-99-05, contained the following types of statements:

> Results achieved in Phase II CINV studies suggest that palonosetron is safe and effective in preventing nausea and vomiting following emetogenic chemotherapy, especially during the first 24 hours after administration.

> Given the high affinity of palonosetron for the 5-HT3 receptor and efficacy results in both animal models and in Phase II studies, a single dose of palonosetron is expected to control acute CINV following moderately and highly emetogenic chemotherapy. Furthermore, due to the long half-life of palonosetron in humans, a single dose of palonosetron may also be beneficial in controlling the delayed phase (24-120 hours) of nausea and vomiting induced by a chemotherapeutic regimen. This study is designed to support the hypotheses that palonosetron is not inferior to currently available 5-HT3 receptor antagonists and is effective in preventing nausea and vomiting following moderately emetogenic chemotherapy. . . .

(See DTX-0293-0030 (PALO-99-03); see also id. at -0149 (PALO-99-04); id. at -0257 (PALO-99-05, replacing "moderately emetogenic" with "highly emetogenic").)

7. Commencement of Phase III trials

All three Phase III clinical trials were performed by a German contract research organization named Kendle GmbH & Co. ("Kendle"). (See DTX-0293-0001 to -0007; DTX-0288-0003; dkt. 322 at 54.) The April 7, 2000 protocol application specified that the "name and title of the person responsible for monitoring the conduct and progress of the clinical investigations" was Alberto Macciocchi, MD, Senior Manager, Product Development at Helsinn. (DTX-0293-0004.) Dr. Macciocchi was still in that position as of July 19, 2002, the date of the Clinical Study Report for the earliest-completed trial, PALO-99-03. (DTX-0288-0003 to -0004.) See n. 16 supra.

The patient participation in the three Phase III clinical trials began with the earliest of those trials,

PALO-99-03. According to the Clinical Study Report at the end of that trial, the Study Initiation Date ("first patient in date") for PALO-99-03 was August 1, 2000. The Study Completion Date ("last patient out date") for that trial was October 2, 2001. (Id. at -0003.) Neither of the other two Phase III trials had a data "locked" date prior to the critical date of January 30, 2002. See Section I.C.11. Therefore, much of the evidence in this chronology focused on the progress of PALO-99-03.

In September 2000, just as the first of the three Phase III clinical trials began, Helsinn issued a press release entitled "Helsinn Announces That Patient Enrollment For Phase III Palonosetron Trials Progresses Both in the USA and Europe." (DTX-1227-0001.) That publication stated, inter alia:

> "The Phase II trials demonstrated the efficacy of Palonosetron in the prevention of emesis with no significant side effects . . . ," said Luigi Baroni M.D., Director of Scientific Affairs. "We are now eager to complete the data necessary for NDA filing scheduled for early 2002."

(Id.)[25]

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[25] The September 14, 2000 Helsinn press release also stated: "'Upon market approval, Helsinn will be in a position to supply its marketing partners with a finished product ready for distribution,' said Giorgio Calderari, Director of Technical Affairs. Helsinn is seeking marketing partners for this patented product in different territories." (DTX-1227-0001.) The reference to "seeking marketing partners" is a topic covered in the trial evidence in some detail, as discussed in Section I.C.9. The words "patented product" appear to relate, at least in the United States, to the original '333 genus patent on the palonosetron molecule, which would not expire until 2015.

8. The SP agreements

Returning to the topic of contracting, it will be recalled that Oread had suddenly closed down in or about June 2000, just before the Study Initiation Date for PALO-99-03, and with the other two Phase III clinical trials gearing up as well. As a result, Helsinn needed to find another organization to pick up Oread's functions and move forward with it in the development project. Dr. Calderari testified that Helsinn then hired SP Pharmaceuticals L.L.C. ("SP"), "essentially, . . . to finish the work that we started with Oread . . . ." (Dkt. 320 at 196.)

A document later submitted to the FDA as part of Helsinn's NDA filing summarized that portion of the drug product development history as follows:

> Oread . . . was selected as the manufacturing site for the formulation of the injectable solution for Phase 3 clinical supplies and for the manufacturing of commercial batches (reference IND amendment serial #064, 19 August 1999). A Commercialization Development Plan was agreed with the Agency during the End of Phase 2 Meeting, 10 March 99, and enacted to complete the transfer of the manufacturing technology for the optimized drug product formulation from Syntex to Oread, Inc.
>
> Due to the subsequent closure of the Oread manufacturing facility in June, 2000, SP Pharmaceuticals, Albuquerque, New Mexico, was selected as the site of manufacture for future NDA commercial drug product, as well as additional Phase 3 clinical batches. No significant changes in the manufacturing process or equipment occurred with the site transfer. Reference is made to IND Amendment Serial #95, 22 Nov. 2000,

> which was submitted in support of SP Pharmaceuticals as the site of manufacture for commercial product.

(DTX-0310-0005, -0006 (footnotes omitted).)[27]

Dr. Calderari stated that Helsinn's contractual relationship with Oread never advanced to the point of any serious negotiations or contracting regarding Oread as a manufacturer of any palonosetron commercial product (despite Helsinn's apparent designation of Oread to the FDA in March 1999 as the "selected" site for such manufacturing). (Dkt. 322 at 125–26.) Dr. Calderari characterized the Oread agreement as a "fee for service agreement." (Id. at 122.) Nevertheless, the above-quoted FDA filing statement indicates that during the Phase III process, Oread was at least identified by Helsinn to the FDA as the "selected" site for future commercial manufacturing.

The first agreement that Helsinn entered into with SP, even before Oread totally stopped functioning, was a Secrecy Agreement dated April 10, 2000. (PTX-361.) It was followed by a "Letter of Intent" designated "Confidential" ("SP Letter of Intent"). (DTX-0258-0002.) The SP Letter of Intent was signed by SP on October 19, 2000, and was signed by Dr. Calderari for Helsinn on November 7, 2000. (Id. at -0004.)

The SP Letter of Intent stated that the parties were "in the process of negotiating a Master Services Agreement for development or manufacture of pharmaceutical products," and they agreed that SP would begin such work, subject to the terms of the Letter of Intent and any

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[27] The Helsinn agreements with SP, referred to in this quoted FDA filing, are described below in this Section.

Scope of Work documents they would mutually agree to in writing. (Id. at -0002.) Attached to the Letter of Intent, signed by the parties on the same dates as the Letter of Intent itself, was a Scope of Work description (id. at -0006 to -0020), and an Appendix A: Pricing and Technology Transfer. (Id. at -0021 to -0023.)

The Scope of Work stated, among other things, that SP "will manufacture Product meeting the Specifications . . . and perform such other responsibilities detailed" therein. (Id. at -0006.) It described that Helsinn would "furnish SP with sufficiently tested and released API to guarantee filling the theoretical batch size. . . ." (Id.) It stated that SP would furnish the vials and the listed incipient raw materials (the EDTA, mannitol, citric acid, etc.), along with related documentation, and would "manufacture the product according to the approved master batch record." (Id. at -0010.) It also provided that SP would do specified quality testing on the finished products, described as 0.05 mg/ml and 0.15 mg/ml (id. at -0012, -0013), and would do stability testing on "Product: Palonosetron-HCl IV injection 0.25 mg/vial & 0.75 mg/vial." (Id. at -0013, -0014.) Among other provisions, it also stated:

> **J. Commercial Product Validation.** SP will perform the following process validation, manufacturing and stability activities to prepare for product commercialization.
>
> 1. Manufacture 3 lots of up to 50,000 vials of Palonosetron-HCl intravenous injection for commercial product validation and sale.
>
> . . . .

2. Perform stability studies on the commercial product validation lots.

. . . .

(Id. at -0015.) There was also an Appendix A: Pricing and Technology Transfer, describing some batches that were going to be manufactured by SP and a price for those batches, including "[m]anufacture up to 10,000 vials of the . . . finished drug product." (Id. at -0021, -0022.)

Dr. Calderari testified that the SP Letter of Intent and attached Scope of Work document did not actually provide for SP to manufacture any commercial product for Helsinn. (Dkt. 322 at 129.) He explained that it provided that Helsinn would pay SP for each activity mentioned in the Scope of Work, including to manufacture the batch size Helsinn was requiring them to manufacture at the time. (Id.) He said that the purpose of the SP Letter of Intent was "a development agreement to make some batches, to test them, to put on stability, and possibly to use in clinical trials." (Dkt. 320 at 196.) He confirmed that SP did actually do the work of creating development batch lots and clinical lots under the SP Letter of Intent. (Id.)

Dr. Calderari said that it was only after the critical date, on June 24, 2002, that Helsinn and SP entered into an agreement for future commercial manufacturing. (Dkt. 322 at 129.) That agreement is identified in the margin.[28]

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[28] On June 24, 2002, a formal Development and Manufacturing Agreement was entered into between SP and the Helsinn subsidiary in Ireland, Helsinn Birex Pharmaceuticals Ltd. (DTX-0259.) That Agreement also contained confidentiality provisions. (Id. at -0024, -0025). At that time, any FDA approval of a Helsinn palonosetron product was still in the future, but this Agreement set the

It is undisputed, however, that as part of its eventual NDA filing, Helsinn recounted that as of November 22, 2000, Helsinn had filed an amendment to its Phase III IND application informing the FDA that "SP Pharmaceuticals, Albuquerque, New Mexico, was selected as the site of manufacture for future NDA commercial drug product, as well as additional Phase 3 clinical batches." (DTX-0310-0006.) See n. 27 supra and accompanying text. The NDA contained, as required, detailed descriptions of the "Selected Manufacturing Process" that SP would perform to make the proposed commercial product, as well as an explanation of the differences between that commercial process and the manufacturing processes SP would use to make "registration batches," that is, clinical trial formulations. (See DTX-0310-0241 to -0243.)

Dr. Calderari explained that as part of the Phase III clinical trial process, the FDA required Helsinn to show three batches of product formulation manufactured at the intended site of commercialization, tested for at least 12 months of stability. He said the FDA would not consider the Oread stability data for that purpose because Oread was no longer the intended site of commercialization. Therefore, the FDA required three batches made at the SP site to be tested for stability, to demonstrate quality control at the SP plant before Helsinn could submit an NDA application. He recalled that process was accomplished using SP, at its manufacturing site, and Helsinn had that stability data available in approximately the second half of 2002. (Dkt. 322 at 155–56.)

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terms for that eventuality. (See id. at -0003, defining "Commercial Product" as "the Product once it has been approved by a Health Authority for commercial marketing in a Territory.")

9. The MGI Agreements

The topic of contracting continued to be a feature of Helsinn's drug product development process after the first of the Phase III clinical trials began on August 1, 2000. Having secured, on a confidential basis, the assistance of first Oread and then SP for the functions those companies performed, Helsinn was also simultaneously in search of "marketing partners," as announced in its September 14, 2000 press release. See n. 26 supra.

Riccardo Braglia, who succeeded his father as CEO of the Helsinn companies, testified (in deposition excerpts in evidence) that their business model is "to licensing-in, develop, and licensing-out." (Dkt. 330 at 54.) He said "we are looking to opportunities of product which are in the . . . early stage of development or middle stage of development, and also are good opportunities." (Id.)

He mentioned two goals of the licensing-out efforts for the palonosetron project: first, to bring in license fees and thus minimize financial risk of such huge investments for Helsinn, and second, to plan for marketing and distribution of product in the United States after FDA approval. (Id. at 54–64.) He said that the "commercial partner" agreement that Helsinn normally did with its partners around the world would feature an up-front payment to Helsinn when the agreement was signed, as well as "milestone" payments (also to Helsinn) at certain points in the development or filing or approval of certain products. (Id. at 57.) He added that for the palonosetron project, as Helsinn discovered the process was much more costly than anticipated, "the strategy was to find as soon as possible a partner that will give us some milestones [i.e., milestone

payments] for the . . . licensing rights to the U.S. market." (Id. (bracketed text added).)

Helsinn conducted a lengthy and arduous search for a willing "commercial partner" for the U.S. market, described by Helsinn employee Dr. Rachid Benhamza at trial, which resulted in written agreements with MGI Pharma, Inc. ("MGI"), a Minnesota company. (Id. at 82-149.) Those agreements, both effective on April 6, 2001, were a License Agreement between MGI and Helsinn (DTX-0115) ("MGI License Agreement"), and a Supply and Purchase Agreement between MGI and Helsinn Birex, the Irish subsidiary. (DTX-0261 and DTX-0311 (same) ("MGI Supply Agreement").)[29]

Dr. Calderari, who participated in negotiating those agreements, described the general nature of the License Agreement as follows:

> [I]t's our standard practice that we grant the rights to a company to explore a patent, and with this, they pay us some licensing fees, and they then will pay us for future royalties on the sales. Concomitant, but subject to this licensing agreement, we also make a supply and purchase agreement that we set the stage for future supplies, once we arrive to get an approval, and also there the price is subject to the price that the company will achieve selling the product on the market. Now, of course, if the license agreement is not there because

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[29] The MGI License Agreement recited that the parties had entered into a Secrecy Agreement on May 25, 2000, and a Letter of Intent on October 5, 2000, under which they had exchanged confidential information and performed due diligence. (DTX-0115-0004.)

> the product would have been unsuccessful in Phase III, then the supply agreement would not be there.
>
> . . . .
>
> [F]or MGI, it was quite clear that this was a developmental . . . . product, so they were not buying a product. They were buying the rights to participate in the development effort to potentially have a product in the future.
>
> . . . .
>
> They paid licensing fees for the licensing agreement, for granting the right, for entering in the agreement. . . . And that helped to continue . . . the clinical trials, because we were still doing the clinical trials. . . .

(Dkt. 320 at 212-14.)

His testimony about the nature of the MGI Supply Agreement, under questioning by counsel for Teva, stated in pertinent part:

> Q. Let's go . . . to the Supply and Purchase Agreement, DTX-0311 . . . . So here we're talking about purchasing products; is that right?
>
> A. Yes. This would set the stage of future purchase of product in the event that we would get to an approval of one or the other, if any, of the formulations that we were studying in the clinical trials.
>
> . . . .

Q. . . . . It says, in 2.1, "Throughout the term of this agreement, . . . MGI undertakes to purchase exclusively from HBP" . . . . "and HBP undertakes to sell to MGI, MGI's entire requirements of the products to be distributed, promoted, marketed and sold by MGI or MGI's affiliates under the License Agreement." That's what the agreement was?

A. Yes. In case there would have been sales, then they would have to purchase from HBP.

. . . .

Q. [W]e just looked at IND 39,797, Amendment 64 . . . . And it set forth two . . . possibilities for a product, one of which was the formulation that is set forth in the patent in this case, is that right?

. . . .

A. In the IND 39,797, they will describe two products, 0.25 and 0.75 milligrams.

Q. And one of them, the .25, is the formulation that's contained in the patents that are at issue in the lawsuit; is that right?

A. Correct.

Q. . . . . it says that whatever will be the product that would be approved – registration . . . means market approval – then we will supply whatever will be the product that will be approved.

Q. Right. And it says what the current products are?

A. Yes. This is a description of the current product that were . . . in this Amendment, in the clinical trials.

Q. Which you're seeking approval on at the time you signed this agreement?

A. We were, but we were making the clinical trials, yes.

Q. And which you expected to get approval on?

A. Well, we had the hope. I mean –

Q. Well, you wouldn't have entered this agreement if you didn't expect to get approval, right?

A. No.

Q. And so the products, . . . if you look at Article 2.1, that's the definition of products, and then it says, "MGI undertakes to purchase exclusively from HBP,". . . and HBP undertakes to sell to MGI, "MGI's entire requirements of the products." That's what the agreement is about?

A. Yes. The product that would be approved, yes.

Q. And a price was agreed to, or a pricing scheme was agreed to with respect to these products? Isn't that correct?

A. Yes. . . . It was setting the stage for the future – I mean, for regulating the purchase process when the product would have been approved, if approved.

(Dkt. 320 at 210–19.)

The definition of "Products," identical in form in the MGI License Agreement and the MGI Supply Agreement, stated:

> "Products" means the pharmaceutical preparations for human use in I.V. dosage form, containing the Compound as an active ingredient [referring to palonosetron hydrochloride] in the formulation which will be described in the Registration [defined as regulatory approval to market the Products]. The current formulation as submitted to the Food and Drug Administration . . . in the IND 39,797 Amendment #64 . . . is described in the [First Appendix of MGI Purchase Agreement; Third Appendix of MGI License Agreement] hereto.

(DTX-0115-0007 (License Agreement); DTX-0311-0006 (Supply Agreement) (bracketed text added).)

The Appendix referred to in the above-quoted definition, identical in both Agreements, read as follows:

> **THE PRODUCTS**
>
> Qualitative description of the Products as submitted to the United States Food and Drug Administration under IND 39,797 Amendment #64. . . .
>
> 1.Palonosetron HCl Intravenous injection is supplied as a sterile, isotonic solution in 5 ml Type I clear glass vials each containing 5 ml of product. The product is clear and colorless solution, and contains the equivalent of either 0.05 mg/mL or 0.15 mg/mL of Palono-

> setron free base. The formulation also contains mannitol as a tonicifying agent, edetate disodium as a chelating agent and citrate buffer to maintain the pH of the solution at the target pH of 5 (±0.5).
>
> 2. The product is terminally sterilized.

(DTX-0115 (License Agreement) at 84; DTX-0311 (Supply Agreement) at 28.)

Both Agreements also contained parallel and mutual confidentiality provisions, of which the following text is representative:

> MGI shall treat as strictly confidential, and shall use solely for the purpose of and in accordance with this Agreement, any and all information, data and/or document received hereunder . . . not generally known to the trade (all hereinafter referred to as the "Confidential Information"). MGI shall not make such Confidential Information available to any third Party, including any of its Affiliates, except to competent government agencies to which it will be necessary to disclose such information, and in this case (a) strictly to the extent requested by said agencies and (b) only upon exercise of its best efforts to cause said agencies to maintain confidentiality.

(DTX-0311 (Supply Agreement) at 18.)

MGI Pharma, Inc., is a publicly-traded company required to file SEC disclosures. A published SEC Form 8-K reported:

> On April 6, 2001, MGI PHARMA, INC. . . . announced that it had entered into definitive agreements with

> Helsinn . . . pursuant to which Helsinn granted to the Company exclusive license and distribution rights to the product candidate palonosetron in the United States. . . . Under the terms of the license agreement, the Company will make $11 million in initial payments, ... and will make additional payments to Helsinn based on the achievement of development milestones. The Company will also pay royalties to Helsinn based upon set sales. Under the terms of a related supply agreement, an affiliate of Helsinn will supply the Company's requirements of finished product. The Company will pay the affiliate product supply fees based upon net sales. The term of each of the agreements is ten years from the launch of the commercialized product, unless earlier terminated by the parties.

(DTX-0367-0002.)

Redacted copies of the MGI License Agreement and the MGI Supply Agreement were attached as exhibits to that Form 8-K report. The Appendix to each agreement that identified **"THE PRODUCTS,"** quoted above, was not attached to that public filing. (DTX-0367 (passim).) What was attached as an exhibit to the MGI Form 8-K report, and incorporated into that Form 8-K report, was the press release dated April 10, 2001 announcing the execution of those agreements, quoted in the margin. (See DTX-0367-0002.) Neither the publicly disclosed MGI Form 8K documents nor the Helsinn/MGI April 10, 2001 press release disclosed the formulations being tested in the Phase III trials.[30]

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[30] The April 10, 2001 press release stated, inter alia,

10. Status of Phase III clinical trials on January 30, 2002

The designs of the three Phase III clinical trials were similar, with differences in the comparator drug (ondansetron in Studies 99-03 and 99-05; dolasetron in Study 99-04) and in the nature of emetogenic chemotherapy agent (moderately emetogenic in Studies 99-03 and 99-04; highly emetogenic in Study 99-05). (See DTX-02930001.) Each of those studies was designed with the two selected palonosetron dose levels of 0.25 mg or 0.75 mg. (Id.) The CRO responsible for the trials was identified as Kendle International Inc., with headquarters in Munich, Germany and Cincinnati, Ohio. (See, e.g., DTX-0293-0036.)

The Study Design section of the PALO-99-05 protocol, which was representative of the designs for the other two Phase III trials, summarized the design of that study as follows:

> **Palonosetron is a potent and selective 5-HT3 antagonist with an extended half-life, in Phase 3 development for the prevention of chemotherapy-induced nausea and vomiting** (CINV). Completion of Phase 3 trials could allow for NDA (New Drug Application) submission in the first half of 2002. When launched, palonosetron will compete in the $1 billion North American CINV market.
>
> . . . .
>
> Based on the extended half-life of palonosetron and the results of the Phase 2 trial, its efficacy will be assessed over Day 2 through Day 5 following treatment, in addition to the primary efficacy measure of complete response during the 24-hour period after the start of chemotherapy.

(DTX-1022-0002 (emphasis in original).)

> This is a multicenter, Phase III, randomized, balanced, controlled, doubleblind, double-dummy, parallel, stratified, and active comparator study design comparing the efficacy, safety and tolerability of single IV doses of palonosetron, 0.25 mg or 0.75 mg, with a single IV dose of ondansetron 32 mg, in the prevention of highly emetogenic chemotherapy-induced nausea and vomiting. The active comparator, ondansetron 32 mg, is the FDA-approved IV regimen for the prevention of nausea and vomiting following highly emetogenic chemotherapy. This dose is also used in Europe for the prevention of CINV. Implementation of published historical placebo controls will be used to validate the trial, demonstrating its sensitivity. It is anticipated that 80 investigative centers will participate in this study; 40 centers in Europe, 35 centers in the United States and 5 centers in Canada. The list of the investigative centers will be distributed to all parties involved in the trial.

(DTX-0293-0263.)

The first-completed Phase III trial was PALO-99-03, as previously stated, with a "last patient out" date of October 2, 2001. (DTX-0288-0003.) The "last patient out" date of PALO-99-04 was December 27, 2001. (DTX-0289-0002.) The "last patient out" date of PALO-99-05 was December 31, 2001. (DTX-0290-0002.)

The final reports of those studies, entitled "Clinical Study Reports," were all dated after January 30, 2002, as described below. See Section I.C.11. Contents of those final reports, however, gave information about the designs and procedures of the studies when the studies were approved by the FDA initially, and later amendments.

The Clinical Study report for PALO-99-03 stated that there were 571 patients enrolled, in 58 active testing centers: 16 centers in Germany, 10 in Italy, 2 in the United Kingdom, 7 in the Netherlands, and 23 centers in Russia, subdivided by region in Arkhangeisk, Moscow and St. Petersburg. (DTX-0288-0006.)[31]

The PALO-99-03 Clinical Study Report, in its Synopsis, also gave an overview of the statistical methods chosen to analyze the data generated in the clinical trials, as quoted in the margin.[32]

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[31] The comparable portion of the PALO-99-04 Clinical Study Report stated there were 592 patients enrolled, and 61 study centers in the United States and Mexico. (DTX-0289-0005.) Likewise, the PALO-99-05 Clinical Study Report said it had 680 patients enrolled, and 76 centers in Europe, Russia, United States/Canada, and Mexico. (DTX-0290-0005.)

[32] The PALO-99-03 Clinical Study Report contained a Synopsis that described the statistical methods used in analyzing the data, stating in part as follows:

> The primary efficacy variable was the proportion of patients considered to have achieved a complete response during the first 24 hours after administration of chemotherapy. The analysis based on the ITT cohort [563 patients] was considered as a primary analysis. To demonstrate the non-inferiority of at least 1 dose of palonosetron to ondansetron, the lower bound of the 97.5% confidence intervals (CI) for the difference (palonosetron minus ondansetron) between the proportion of patients with complete response (CR) during the first 24 hours after administration of chemotherapy was calculated and compared to the pre-set threshold (-15% difference). Moreover, to investigate the equivalence of the 2 palonosetron doses with respect to CR (0 to 24 hours) the bound of the two-sided 95% CI of the difference between the proportions of CR (0 to 24) were compared to the pre-set threshold (±15%). The validation/study sensitivity as as-

The evidence presented at trial established that the following sequence of events occurred during the period of time between the PALO-99-03 "last patient out" date, October 2, 2001, and the critical date (for on-sale bar purposes) of January 30, 2002.

An explanation of some of the PALO-99-03 documents was provided at trial by Helsinn expert witness Dr. Carl Peck. He is an M.D. with experience in internal medicine, pharmacokinetics and biostatistics, whose background included a six-year period as the director of the FDA's Center for Drug Evaluation and Research ("CDER"), the division with responsibility for all drug applications for human administration. He also has a current "special government employee" consulting status with the FDA. (Dkt. 337 at 4–16.)

Reviewing the PALO-99-03 files in evidence and the underlying documentation, Dr. Peck described the work that was done after the clinical study with patients closed on October 2, 2001. Here is his summary of the next few

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sessed by comparing CR (0 to 24 h) of the active control ondansetron with modeled historical placebo results and modeled historical ondansetron results from the literature. Complete response at further time points was analyzed using the same statistical methods as for the primary efficacy parameter. Complete control and the proportion of patients receiving rescue medication were analyzed using the Chi-square test. Furthermore, Poisson regression analysis was performed for the emetic episodes taking into account if rescue medication was administered. Quality of life, number of emetic episodes, severity of nausea and patient global satisfaction were compared between the treatment groups using the Kruskal-Wallis test or the Wilcoxon test.

(DTX-0288-0008 (bracketed text added).)

steps in the PALO-99-03 process after that "last patient out" date:

> There is no fully assembled, blinded or unblinded data set at that moment. That's a milestone in the execution of a clinical trial, and if you think about it in a multi-center, multi-national clinical trial, there's a lot to do with respect to gathering the data from each site, making sure that the data has been entered properly. In this case, I have read in the protocol that all the data was collected on handwritten case report forms, so those had to be translated into a computer. They used a double entry system, meaning that two independent persons take the data from the case report form and put it into the computer. Those have to be assembled in each center, then they have to be sent to the CRO, Kendle in this case in Munich, which will assemble them all, and then . . . begin to evaluate the quality. This is all well articulated in the protocol, because regulatory agencies and a POSA would require that if you're going to analyze the data for this purpose, it's got to be high quality. It's got to be verified. The company was even doing site visits during that period of time at some of the sites. In fact, one collection of sites was in Russia. One was up near the border of Siberia, and there was a site visit on that very site after the last patient out in order to validate that everything had been done right at that site.
>
> . . . .
>
> The CRO is doing this, although sometimes the company will commission an independent quality assurance company to do this as well. There were actually a handful of CROs that were working for Helsinn on contract, located in different countries, who were

> working on the whole execution and assembling of the data.
>
> . . . .
>
> What we see here or what we know about these three trials is that it took about eight weeks. That's most clearly shown in the study report for the 99-03 in which there's a meeting that's identified that happened on December 11th and 12th of 2002 [sic: 2001], in which the data quality committee got together to discuss all of the assembled data.
>
> . . . .
>
> [That] whole process is called blind data review, but the meeting in December, it was sort of the final summit meeting of the independent evaluators who were qualifying the data.

(Dkt. 337 at 65–67.)[33]

Dr. Peck testified that the two-day "blind review" meeting was conducted independent of Helsinn, and Helsinn did not participate in any of the blind data review. (Id. at 67–68.) Dr. Peck said that meeting resulted in a formal protocol amendment submitted to the FDA on December 13, 2001, revising the study groups that would be analyzed for efficacy, as described in the Final Study Report. (Id. at 67–68, 165–66.)

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[33] Dr. Peck stated that the PALO-99-03 blind review meeting was on December 11 and 12, 2002, as cited above. The meeting was actually on December 12 and 13, 2001. (See DTX-0288-0056.) He apparently misspoke the date, but the record is clear.

The PALO-99-03 records state that after the "blind review" meeting, the database was closed on December 19, 2001. (DTX-0288-0056.) Dr. Peck referred to that as when the data was "locked." (Dkt. 337 at 66.) Dr. Calderari testified that he did not see any of the blinded data results, and he did not know whether anyone else at Helsinn saw blinded results after the last patient out date of the PALO-99-03 study. (Dkt. 322 at 56–57 (bracketed text added).)

Dr. Peck was asked whether the clinical study data could change during the period immediately after the "last patient out" date. He said:

> [T]he raw data can change during that period of time, yes. Because if they discover a blunder, [if] they discover that the data was not legible, if they find that one of the patients actually got the wrong drug, there's a lot of things that can happen during the data quality evaluation that can lead to changing actually the raw data. It's only after the raw data have been qualified and the database locked, what they call locked – and that's the point in time where they have decided that, yes, we've done all of the quality control . . . that we possibly can and we think this data is valid.

(Dkt. 337 at 66–67.)

The PALO-99-03 documents list January 2, 2002 as the "unblinding" date, which Dr. Peck said was the first date that the sponsor, Helsinn, would have been allowed to see the data. (Id. at 164–65; see DTX-0288-0056.) However, the data was only in preliminary form at that time, and much analysis remained to be done on that one study

alone, according to Dr. Peck's explanation quoted in the margin.[34]

Dr. Calderari recalled that the unblinded preliminary data on PALO-99-03 were sent to Helsinn [by the CRO conducting the study] in January, 2002, and that preliminary data "show efficacy for the product." (Dkt. 322 at 61.) He said that was a happy day at the company; "we were start seeing that our effort were paying off, but, of course, we were very careful because they were preliminary data." (Id.)

Helsinn sent a letter to CDER dated February 7, 2002 (the week after the critical date of January 30, 2002), stating in part as follows:

> In accordance with 21 CFR 312.47(b)(2), a pre-NDA meeting is requested in preparation for the palonosetron NDA. All phase 3 efficacy trials . . . have completed enrollment and preliminary efficacy data are available.

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[34] Dr. Peck described the process of analysis that spanned the period from the "unblinding" date to completion of the final study report as follows:

> The moment of unblinding, the data sets are now available for analysis. There's a mountain of data in this clinical trial. 600 – or 500 and some patients, each patient observed for various values of one sort or another, including vomiting, probably 2 to 300 times. If you count the data items themselves, it's humongous. You don't just push a button and, bingo, there's your full study report ready to go to FDA. It's a very tedious effort. And even along the way, if they have not confirmed that certain assumptions were made with respect to the statistical analyses, they may go back to FDA and talk about . . . an alternative analysis.

(Dkt. 337 at 73–74.)

> Consistent with your letter of October 10, 2001, please find attached at Appendix #1 preliminary efficacy data for PALO-99-03. In this study, the preliminary data for Complete Response, which is the primary efficacy outcome measure for acute CINV, was 81.0% (153/189) for palonosetron 0. 25 mg, 73.5% (139/189) for palonosetron 0.75 mg, and 68.6%(127/185) for ondansetron 32 mg. Preliminary efficacy results for PALO-99-04 will be included in the background information package projected to be submitted four weeks prior to the meeting, and preliminary efficacy data for PALO-99-05 will be presented at the meeting.
>
> The following product information is provided to you regarding the suggested meeting:
>
> **Product name and application number**: Palonosetron HCl Intravenous Injection, 0.25 mg (0.05 mg/mL), or 0.75 mg (0.15 mg/mL). Please note that one of these product strengths will be selected for marketing approval based on the phase 3 efficacy data. The NDA number is 21-372.

(DTX-0264-0001.)

The tables of "preliminary efficacy data" attached to that Helsinn letter to the FDA dated February 7, 2002 letter were dated January 7, 2002. (Id. at -0009 to -0011.) Dr. Calderari testified that he could not recall when he first saw the data in those tables, but he would assume that he did see the data before January 15, 2002. (Dkt. 322

at 72.) Portions of two of those charts are shown in the margin.[35] See n. 37 infra and accompanying text.

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[35] The tables attached to the February 7, 2002 Helsinn letter to the FDA, described as PALO-99-03 preliminary data, included the following content:

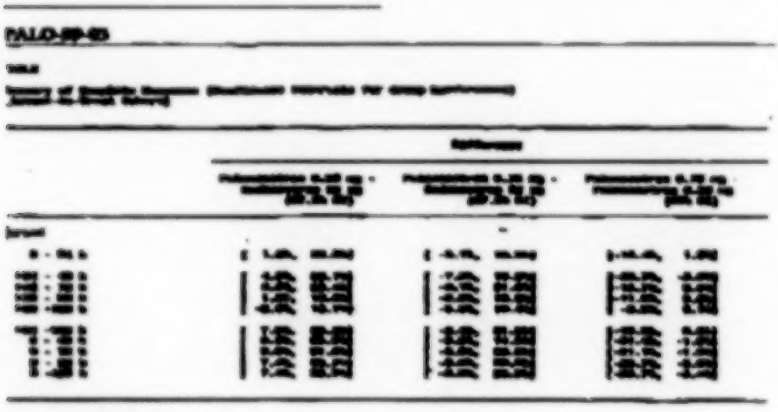
PALO-99-03

[redacted]

(DTX-0264-0009.)

A further explanation of portions of the PALO-99-03 documents was provided at trial by Teva expert witness Dr. John Fruehauf. He is an M.D. clinical oncologist who also has a Ph.D. in pharmacology. He is a professor of clinical medicine and director of clinical pharmacology and developmental therapeutics at University of California Irvine. He has an active practice at the Chao Family Comprehensive Cancer Center, one of 43 comprehensive cancer centers in the United States. As director of developmental therapeutics, he is regularly involved in conducting Phase I, Phase II, and Phase III clinical trials. (Dkt. 324 at 5–8.)

Dr. Fruehauf and Dr. Peck testified as to their conflicting opinions on whether a person of ordinary skill in the clinical sciences would know, as of January 30, 2002, that palonosetron administered to a human reduces the likelihood of CINV, and specifically whether such person would know at that time that the 0.25 mg dosage claimed in the '219 patent was effective for CINV. (See generally dkt. 324 (Dr. Fruehauf); dkt. 337 (Dr. Peck).) That opinion testimony is discussed in Section II.A.4.b.2.



(DTX-0264-0011.)

Testifying about the PALO-99-03 study documents themselves, Dr. Fruehauf stated that it was not surprising to see that the database was "unblinded" on January 2, 2002, and the three summary tables attached to Helsinn's February 7, 2002 letter to the FDA were dated January 7, 2002, less than a week after the data was unblinded. He pointed out that those tables, which do include some statistical analysis, are indicated at the bottom of each page to have been prepared using SAS. (Dkt. 324 at 61–63.)

Dr. Fruehauf explained that SAS is a widely accepted statistical package that was included in the pre-planned protocol for that Phase III study, "so before anybody went on this study, it was determined that this is what they would do." (Id. at 61.) On the other hand, referring to the later PALO-99-04 locked data, he did acknowledge that before the final reports of these Phase III studies were completed, "there were other things, statistics and other things that might be done" to analyze the locked data of those studies. (Id. at 204.)

Dr. Calderari, as head of the Helsinn palonosetron development program but not himself a clinician, was asked whether, upon receipt of that data in early 2002, he formed any conclusion as to whether palonosetron would definitely work for the reduction of CINV. He said no; "that was an indication that the first preliminary data set was positive; but....we, as part of the overall plan, we have to have two pivotal trials to be completed successfully in order to show efficacy of the product, so 99-03 and 99-04." (Dkt. 322 at 137–38.) When asked whether this data gave him confidence that both of those trials would successfully show efficacy, he replied, "[n]o, because unfortunately, as we know very well, drug development, . . . one trial is in-

dependent from the other one. You are also using different investigator, different countries, different populations, so there might be difference between two trials." (Id. at 138.)

Helsinn, together with its U.S. licensee and selected marketing partner MGI Pharma, issued a press release on January 16, 2002. The text of that announcement is quoted in full in the margin.[36]

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[36] The January 16, 2002 press release stated:

> HELSINN HEALTHCARE SA, a privately owned Swiss pharmaceutical group, and MGI PHARMA, INC., (Nasdaq: MOGN) an oncology-focused pharmaceutical company based in Minneapolis, today announced that patient treatment is completed and the data analysis is underway for the pivotal Phase 3 trials of their investigational agent, Palonosetron. **Palonosetron** is a potent, highly selective 5-HT3-receptor antagonist in development in North America and Europe for the prevention of chemotherapy-induced nausea and vomiting (CINV). Submission of the New Drug Application (NDA) for Palonosetron is now planned to occur in the third quarter of 2002.
>
> The Phase 3 clinical trial program was initiated in April 2000 and was designed to compare intravenous (IV) Palonosetron to currently marketed 5-HT3 antagonists. The trials were conducted at more than 130 medical centers across North America and Europe, with more than 1,800 cancer patients receiving either highly-or moderately-emetogenic chemotherapy. Based on the extended half-life of Palonosetron and the results of a Phase 2 trial, the efficacy of Palonosetron in the Phase 3 trial is being assessed over Day 2 though Day 5 following treatment, in addition to the primary efficacy measure of complete response during the 24-hour period after the start of chemotherapy.
>
> **"We are pleased to have completed all patient treatment and to have begun analysis of the data collected in the Palonosetron Phase 3 clinical program,"** said Luigi Baroni, senior director of Scientific Affairs Division at HELSINN. **"The Phase 2**

11. Status as of patent application date, January 30, 2003

This section describes the chronology of the further palonosetron drug development events between the critical date of January 30, 2002, and the January 30, 2003 provisional application date of all four patents-in-suit.

It will be recalled that each of the three full-scale Phase III studies had reached the "last patient out" date in the fourth quarter of 2001. The clinical data from the earliest-completed study, PALO-99-03, had been "locked" on December 19, 2001, and had been "unblinded" and therefore available to be viewed by Helsinn on January 2, 2002. See Section I.C.10. The database of PALO-99-04 was locked on February 22, 2002 and that data was unblinded on February 28, 2002. (DTX-0289-0054.) The "locked" date for PALO-99-05 was March 14, 2002, and

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> **clinical trial results were promising, and we are hopeful that the Phase 3 Palonosetron data will demonstrate that it can make a difference for cancer patients suffering from CINV."** "**The half-life of other available 5-HT3 receptor antagonists ranges from approximately five to nine hours, where Palonosetron has a plasma elimination half-life of nearly 40 hours,**", notes Dr. John MacDonald, senior vice president of Research and Development at MGI. "**The activity seen with Palonosetron in the Phase 2 trial, coupled with its safety profile observed to date, led to the initiation of a Phase 3 program to assess the ability of the drug to provide prolonged protection against CINV with a single dose.**"
>
> (DTX-0040-0001 (emphasis in original).)

that data was unblinded on March 19, 2002. (DTX-0290-0023.)

The letter from Helsinn to the FDA, although dated and sent on February 7, 2002, has been described above as falling within the January 30, 2002 critical date period, because the tables of PALO-99-03 preliminary data attached to that letter were prepared and known to Helsinn before January 30, 2002. See Section I.C.10. Presumably that requested meeting with the FDA to review preliminary results of PALO-99-03, as well as preliminary results of PALO-99-04 and PALO-99-05 when available, did take place at a date not specified in the evidence.

The final reports on those three studies were named Clinical Study Reports. Those Reports for PALO-99-03 and for PALO-00-04 were each dated July 19, 2002. (DTX-288-0003; DTX-0289-0002.) The Clinical Study Report for PALO-00-05 was dated August 2, 2002. (DTX-0290-0002.) The Analysis Report of the re-analysis of Phase II study 2330 data, entitled "Fixed Dose Conversion and Historical Placebo Control Post-Hoc Efficacy Analysis (code PALO-00-01)," was dated August 8, 2002. (PTX-182.0003.)

The Clinical Study Report for PALO-99-03 was 250 pages long, exclusive of appendices. That report, with appendices, occupied 17 volumes in the subsequent NDA filing. (See DTX-0288-0003 and -0013 to -0018.) The Clinical Study Reports and appendices for PALO-99-04 and PALO-99-05 were comparable documents. (See DTX-0289 and DTX-0290.)

The Conclusion in the Synopsis section of the PALO-99-03 Clinical Study Report stated:

> In this study, non-inferiority of the 2 doses of palonosetron (0.25 mg and 0.75 mg) to ondansetron 32 mg was demonstrated for the complete response rate during the first 24 hours after chemotherapy, the primary efficacy parameter. Furthermore, non-inferiority of both palonosetron groups compared to ondansetron was also shown for most secondary efficacy parameters and palonosetron 0.25 mg was shown to be superior to ondansetron with regard to most of these secondary efficacy parameters. Thus, palonosetron 0.25 mg showed a better efficacy profile over ondansetron during the delayed phase of nausea and vomiting. The rate of patients with adverse events was comparable in the treatment groups and showed a similar pattern. There were no safety concerns associated with results of laboratory parameters, vital signs and ECG recordings and Holter monitoring measured during the study.

(DTX-0288-0012.) The corresponding Conclusion sections of the PALO-99-04 and PALO-99-05 Clinical Study Reports contained similar types of information. (See DTX-289-0012; DTX-0290-0011.)

The Synopsis section of the PALO-99-03 Clinical Study Report also contained exactly the same efficacy summary numbers that had been communicated to the FDA in the preliminary data tables attached to Helsinn's letter dated February 7, 2002. See n. 35 supra. Those numbers were set forth in Table 1 and Table 2 of the Syn-

opsis, as also contained in the appendix materials submitted with that Report. (See DTX-0288-0009 and -0095.) Those two tables are shown in the margin.[37]

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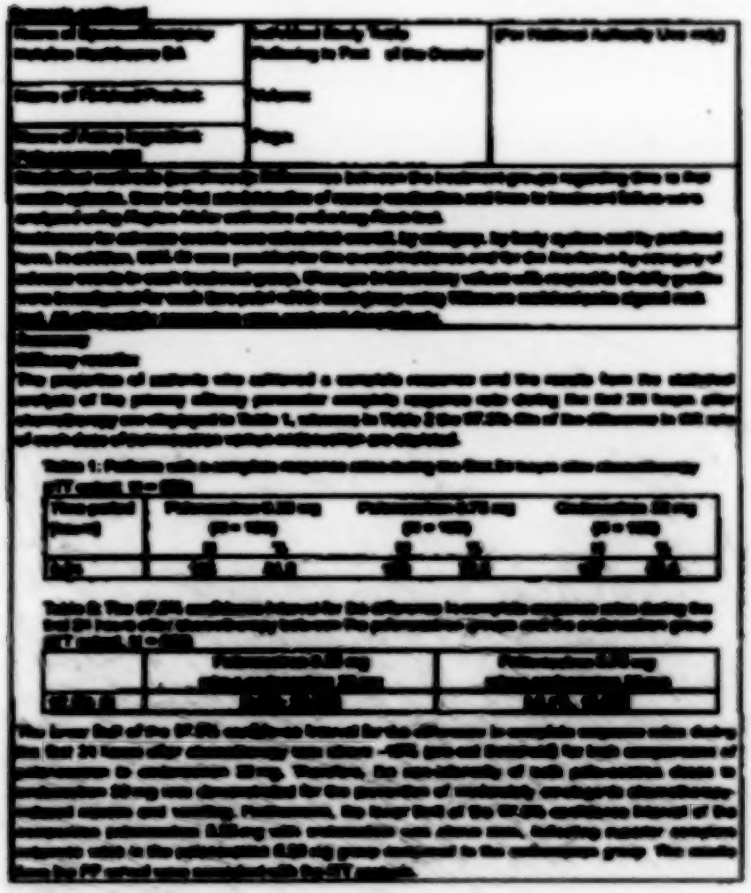
[37] The tables shown under "Efficacy results" in the Summary portion of the Synopsis section of the PALO-99-03 Clinical Study Report were as follows:



(DTX-0288-0009.)

The detailed contents of the PALO-99-03 Clinical Study Report, following the Synopsis, included a narrative headed Additional changes after unblinding. Portions of that section are also quoted in the margin.[38]

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[38] That portion of the PALO-99-03 Clinical Study Report stated in part as follows:

> • Additional statistical analyses.
>
> An additional statistical analysis was performed for the number of emetic episodes, which presented the number of patients with 0, 1, 2 and ≥3 emetic episodes for each time interval. Furthermore, quartiles were calculated for quality of life, time to first emetic episode, time to treatment failure, time to the first administration of rescue medication and patients global satisfaction because median, mean, minimum and maximum values did not show the differences between the treatment groups, which were seen by statistical testing. Further additional analyses were performed on dosage and time of infusion of chemotherapy given on Day 1.
>
> . . . .
>
> • Change in the statistical analysis.
>
> The normal distribution of data (number of emetic episodes, patient global satisfaction, quality of life) was to be assessed by the Shapiro-Wilk test before the application of parametric tests. However, the non-normality was obvious form [sic: from] the summary tables. Therefore, the Shapiro-Wilk test was omitted and a non-parametric method was used.
>
> . . . .
>
> • Trial validation.
>
> A new formula for the trial validation was developed because a mistake was detected in the database. Moreover, additional information regarding the percentage of patients in each study treatment arm using concomitant steroids was added. It was decided to consider both formulas (original and updated formulas) for the validation of study PALO-99-03.

(DTX-0288-0071, -0072 (bracketed text added).)

Helsinn filed its New Drug Application, NDA 21-372, on September 27, 2002, approximately one month after the above-listed clinical reports were completed. (See PTX-121.) All of those reports, as well as voluminous other data, were included in that NDA filing. (See NDA number 21-372 on each title page of above-cited report exhibits.) Helsinn sent additional submissions to the FDA dated October 11 and November 21, 2002, January 24, April 9, April 24, May 15, June 9, June 13, June 18, June 20, June 25, July 1, July 17, and July 22, 2003. (See PTX-121.)

Helsinn made at least one publication of some of its unblinded Phase III data during the period between January 30, 2002 and the patent application date of January 30, 2003. That was an oral presentation accompanied by an abstract, authored by Helsinn's Dr. Macciocchi and research colleagues Steven M. Grunberg et al., described as "for the PALO-99-04 Study Group." ("the Grunberg abstract"). It was entitled "Palonosetron is active in preventing acute and delayed emesis following moderately emetogenic chemotherapy: Results of a phase III trial." (PTX-297.0002.)

The Grunberg abstract was presented at the June 23-26, 2002 conference of the Multinational Association of Supportive Care in Cancer in Boston. (PTX-297.0001.) At that time, the PALO-99-04 data had been unblinded and under analysis since February 28, 2002, and the final Clinical Study Report would be completed and dated July 19, 2002. Also, of course, the data of the companion study, PALO-99-03, had been unblinded and under analysis since January 2, 2002, and its Clinical Study Report would also be dated July 19, 2002. See Section I.C.11.

There was text and a table in the one-page Grunberg abstract. The table showed efficacy results of Helsinn's 0.25 mg. and 0.75 mg palonosetron dose levels in comparison with dolasetron, for acute and delayed CINV in moderately emetogenic chemotherapy, as the PALO-99-04 trials had studied. The Conclusion stated in the Grunberg abstract was: "Palonosetron has demonstrated significant activity in preventing both acute and delayed emesis with a single I.V. dose in patients receiving moderately emetogenic chemotherapy. Palonosetron was safe and well tolerated." (PTX-297.0002.)

Helsinn filed Provisional Patent Application No. 60/444,351 at the U.S. Patent and Trademark Office on January 30, 2003. (See dkt. 289 (patent family history chart).) On that date, Helsinn's New Drug Application 21-372 was still pending at the FDA.[39]

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[39] FDA approval of Helsinn's NDA 21-372 was issued on July 25, 2003. The approval letter stated in pertinent part:

> This new drug application provides for the use of Aloxi® (palonosetron hydrochloride injection) for:
>
> 1) the prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy, and
>
> 2) the prevention of delayed nausea and vomiting associated with initial and repeat courses of moderate emetogenic cancer chemotherapy.
>
> We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

(PTX-121.0001, -.0015.)

12. Issuance of patents-in-suit

The procedural history of the prosecution of the patents-in-suit, subsequent to the filing date of the provisional application on January 30, 2003, has been summarized in this Court's claim construction Memorandum Opinion filed in this case on April 22, 2015. (See dkt. 290 at 16–18.) Here we briefly summarize the basic chronology of those prosecution events, omitting record citations that are stated in that earlier Opinion.

The first generation of patents to be issued subsequent to the January 30, 2003 provisional application date were the '724 and '725 patents-in-suit, dated May 24, 2011. Thus, the original prosecution for this patent family took approximately 8½ years. The next patent-in suit, the '424 patent, was issued on June 14, 2011.

The '724, '725, and '424 patents, all sharing a contemporaneous prosecution era, were approved only after appeals in all three cases to the Commissioner of Patents. Much file history was accumulated in those prosecution files.

The '219 patent, with the same provisional application date and an actual filed application date of May 23, 2013, was issued on December 3, 2013. That patent was applied for and granted during the pendency of this litigation. The application history of the '219 patent itself, albeit not as extensive as for the other three patents, includes many of the materials filed in this litigation including expert reports. (See '219 patent, pages 1–6.) The other patents issued to date in this patent family tree, and abandoned applications, are listed in the chart supplied by the parties. (Dkt. 289.)

13. Claim construction rulings regarding prosecution history

This Court has issued claim construction opinions interpreting some claim limitations of the patents-in-suit pertaining to both the stability and the efficacy aspects of the claims. Those opinions were filed during claim construction proceedings in this case and in a related case, Civil Action No. 12-2867.

The claim construction Memorandum Opinion filed in this case, on April 22, 2015, addressed the issue of whether the following portion of the preamble of claim 1 of the '219 patent constitutes claim limitation language: "for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting." This Court ruled that language to be limiting in its entirety. (Dkt. 290.) The discussion in that opinion included a review of portions of the prosecution history of all of the patents-in-suit, as it was recognized that the earlier patent histories can be relevant to interpreting the claims of later-issued patents in the same family.

That opinion described, inter alia, a phase early in the prosecution of the '724, '725, and '424 patents when the examiners rejected the term "preventing emesis" in applied-for preambles to each of those patents under 35 U.S.C. § 112 (enablement). (See dkt. 290 at 20.) The applicants overcame that ground for rejection in each of those applications by substituting the words "for reducing emesis or reducing the likelihood of emesis." (Id.)

To overcome that ground for rejection, the applicants successfully argued as follows, in a telephone interview with the examiners quoted from here in the file history of the '424 patent:

> During the telephone interview, a proposed amendment to the claims in the '270 application was discussed. Applicant understood the Examiner's primary concern with the claims to be with the word "preventing," recited in independent claims 1 and 11 of the '270 application. Applicant indicated that palonosetron has been approved by the Food and Drug Administration for preventing emesis, and is marketed as a drug for preventing emesis.
>
> The Examiners suggested that an amendment to independent Claims 1 and 11 in the '270 application, wherein Applicant includes the phrase "reducing the likelihood" of emesis instead of "preventing" emesis, would address the Office's concerns. Applicant has amended the claims in this application in accordance with the Examiners' suggestions for the '270 application.

(Dkt. 178-3 at 116 (Examiners' Summary of July 27, 2006 Telephonic Interview).)

This portion of the common prosecution history of the patents-in-suit may be relevant to the on-sale bar issues in this case, discussed in Section II.A.4.

14. ANDA filings by Teva and others

Teva's Abbreviated New Drug Application ("ANDA") seeks approval for a generic Aloxi® product that can have one of two dosage strengths: (1) a 0.25 mg/5 ml dosage strength, used to prevent chemotherapy-induced nausea and vomiting ("the CINV dosage strength"); and (2) a

0.075 mg/1.5 ml dosage strength, used to prevent postoperative nausea and vomiting ("the PONV dosage strength"). (See dkt. 207 at 4.) The concentration of both proposed Teva products is 0.05 mg/mL, because the 0.25 mg dose solution is 5 ml and the 0.075 mg dose solution is 1.5 ml.

II. CONCLUSIONS OF LAW[40]

A. On-sale bar

The Court will now turn to the issue of the on-sale bar and its application to this case. "[T]he patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time." Pfaff v. Wells Elec., Inc., 525 U.S. 55 (1998). Before 2011, Section 102 of the Patent Act balanced this "carefully crafted bargain" by providing that:

> A person shall be entitled to a patent unless(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States
> . . . .

35 U.S.C. § 102, amended by Leahy-Smith America Invents Act, Pub.L. No. 112-29, 125 Stat. 254 (2011) (emphasis added) ("AIA"). This provision, referred to as the

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[40] To the extent that the "Conclusions of Law" portion of this opinion contains findings of fact in addition to those expressly set out under the heading "Findings of Fact," they shall be deemed to be part of the findings of fact.

on-sale bar, serves as a bar to patentability if the claimed invention is (1) made the "subject of a commercial offer for sale," and (2) the invention is "ready for patenting." See Pfaff, 525 U.S. at 67. A sale under this bar occurs when the parties offer or agree to reach a contract "to give and pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold." Zacharin v. United States, 213 F.3d 1366, 1370 (Fed. Cir. 2000) (quotation and citation omitted).

1. Legal standards and post-AIA statutory construction

a. Historical analysis

Historically, a secret sale or offer for sale of a claimed invention has precluded patentability under the on-sale bar. See Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co., 153 F.2d 516 (2d Cir. 1946) (Hand, J.) ("[I]t is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly."); Egbert v. Lippman, 104 U.S. 333 (1881). The invention at issue in *Egbert*, a corset improvement, was given by the inventor to a woman who wore the corset under her dress, rendering it unobservable to the general public. See Egbert, 104 U.S. at 337. The Supreme Court found that the inventor's corset improvement was in public use, noting that "[i]f an inventor, having made his device, gives or sells it to another . . . without limitation or restriction, or injunction of secrecy, and it is so used,

such use is public, even though the use and knowledge of the use may be confined to one person." See id.[41]

The legal principle set forth in Egbert—that a claimed invention given or sold to one individual or entity in secrecy can constitute a public use—has proliferated a line of precedent in which secret sales or offers for sale bar patentability. See, e.g., Special Devices, Inc. v. OEA, Inc., 270 F.3d 1353, 1357–58 (Fed. Cir. 2001) (finding that on-sale bar invalidated patent, although contract for sales of invention was only for purpose of commercial stockpiling by supplier and sales were confidential); Woodland Trust v. Flowertree Nursery, Inc., 148 F.3d 1368, 1370 (Fed. Cir. 1998) ("Thus an inventor's own prior commercial use, albeit kept secret, may constitute a public use or sale under § 102(b), barring him from obtaining a patent."); Hall

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[41] The Court notes that pre-AIA § 102 language also included a public use bar. See 35 U.S.C. § 102, amended by § 102(a)(1), 125 Stat. at 285-86 ("A person shall be entitled to a patent unless . . . (b) the invention was . . . in public use . . . ."). As a historical note, the public use and on-sale bars were often not differentiated by courts, or were referred to using other terminology. See, e.g., Metallizing Eng'g Co., 153 F.2d at 520 (borrowing statutory language from Patent Act of 1839 and referring to on-sale and public use bars as "prior use"). The relationship between the § 102 bars was explained by the Supreme Court in Pfaff:

> We originally held that an inventor loses his right to a patent if he puts his invention into public use before filing a patent application. His voluntary act or acquiescence in the public sale and use is an abandonment of his right. A similar reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar.

Pfaff, 525 U.S. at 64 (quoting Pennock v. Dialogue, 27 U.S. 1 (1829) (Story, J.)).

v. Macneale, 107 U.S. 90, 96 (1883) (finding that an inventor's "burglar-proof" safes were in public use after inventor sold three safes, despite testimony that technology was completely concealed within safe).

On September 16, 2011, the AIA was signed into law with the objective of "establish[ing] a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs." (Dkt. 236-3 at 81 (AIA Committee Report).) The AIA's most significant change was the conversion of the United States' patent system from a "first-to-invent" to a "first-inventor-to-file" system, which now "encourages the prompt filing of patent applications" and redefines the effective filing date as the date of the patent application, rather than the date of the invention. See 35 U.S.C. § 100(i)(1)(A) (1-24-2008 Committee Report).[42]

In converting to a first-inventor-to-file system, Congress attempted to modernize and streamline many facets of the patent system, including the identification of prior art. (See dkt. 236-3 at 83–84 (AIA Committee Report) ("Prior art will be measured from the filing date of the application and will typically include all art that publicly exists prior to the filing date, other than disclosures by the inventor within 1 year of filing.").) As discussed above, the on-sale bar analysis under the Egbert rationale had led to unusual or extreme results for patentees who sought to obtain a patent after such secret use or sales. (See id. at 17 (statement of Senator Kyl in Mar. 8, 2011 Congressional Record, in which he describes effect of on-sale bar

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[42] As will be discussed later, Plaintiffs argue that this overall change to the patent system also supports a new interpretation of the on-sale bar.

and public use bar as "impos[ing] extreme results to no real purpose.").)

The AIA thus redefined the scope of prior art under § 102 as follows:

> A person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention . . . .

35 U.S.C. § 102(a)(1).

The AIA added the clause "otherwise available to the public," and also regrouped the categories of prior art under § 102. Compare 35 U.S.C. § 102, amended by § 102(a)(1), 125 Stat. at 285–86 (designating prior art categories as follows: "patented or described in a printed publication in this or a foreign country or in public use or on sale in this country . . . ."), with 35 U.S.C. § 102(a)(1) (designating prior art categories as: "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public. . . .").

b. Parties' arguments regarding on-sale bar

It is against this historical and statutory background that this Court decides whether § 102(a)(1) of the AIA requires a sale or offer for sale of a claimed invention to be "available to the public before the effective filing date" of the claimed invention in order for the on-sale bar to apply

and possibly invalidate a patent. (See generally dkt. 204; dkt. 209; dkt. 226; dkt. 236.)[43]

Plaintiffs argue, as a threshold matter, that the '219 patent is subject to the AIA. (See dkt. 209 at 18–19.) The AIA states in pertinent part:

> [T]he amendments made by this section shall take effect upon the expiration of the 18-month period beginning on the date of the enactment of this Act [September 16, 2011], and shall apply to any application for patent, and to any patent issuing thereon . . . .

35 U.S.C. § 3(n).

Plaintiffs additionally argue that the AIA established a new standard for the on-sale bar, i.e., that commercial sales or offers for sale of the invention must now be made available to the public for the on-sale bar to apply. (See dkt. 209 at 7.) Plaintiffs argue that the contracts with service providers Oread, Inc. ("Oread") and SP Pharmaceuticals L.L.C. ("SP"), and the licensing and supply agreements with MGI Pharma, Inc. ("MGI") were not commercial sales or offers for sale. (See id.) Plaintiffs argue in the alternative that even if this Court considers these contracts to be commercial sales or offers for sale, the post-

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[43] Defendant, in its opposition to Plaintiffs' motion for partial summary judgment, relied in part on Sandoz's motion for summary judgment of invalidity of the '219 patent under the on-sale bar. (See dkt. 226 at 8, n. 1.) Sandoz's motion for summary judgment was terminated by way of a consent judgment but will be cited to in this Memorandum Opinion insofar as Defendant incorporated these arguments into this motion. (See dkt. 247.)

AIA on-sale bar applicable to the '219 patent does not apply because the contracts never made the invention available to the public. (See id.)

Teva argues that the AIA did not amend the on-sale bar to include a public sale requirement. (See dkt. 226 at 9.) Teva asserts that under the correct interpretation of the AIA, Helsinn violated the on-sale bar by executing a supply agreement for the marketing and sale of Aloxi with MGI. (See id. at 10.) Teva additionally argues that Helsinn violated the on-sale bar even under Helsinn's proposed interpretation of the AIA, as the supply agreement was publicized and MGI is a member of the public. (See id.)

c. Interpreting the legal standard

1. Statutory construction

The Court's first inquiry in interpreting a statute "is to determine whether the language at issue has a plain and unambiguous meaning with regard to the particular dispute in the case. Our inquiry must cease if the statutory language is unambiguous and the statutory scheme is coherent and consistent." Bettcher Indus., Inc. v. Bunzi, USA, Inc., 661 F.3d 629, 644 (Fed. Cir. 2011) (quotation and citation omitted).

The parties in this case dispute whether the last clause of § 102(a)(1), "otherwise available to the public," modifies the section's previous clauses or serves as its own category of prior art. (See dkt. 209 at 21 ("Since the modifier 'or otherwise available to the public' in § 102(a)(1) is a catchall phrase, it applies to each preceding category of prior art in that section that must make the claimed invention available to the public, including an alleged 'sale.'"); but see dkt. 226 at 20 ("[T]he phrase 'or otherwise

available to the public' creates a residual category of prior art to capture invalidating disclosures that do not fall into one of the enumerated categories in section 102.").)

This Court is guided by the Supreme Court's "common sense" approach to statutory interpretation. See Paroline v. United States, 134 S. Ct. 1710 (2014) ("Reading the statute to impose a general proximate-cause limitation accords with common sense.").[44] The statute at issue in Paroline included six categories of covered losses and a final clause that covered "any other losses suffered by the victim as a proximate result of the offense." See id. at 1720. The victim argued that the proximate causation requirement only applied to the final "catchall" category in the statute. See id. at 1720–21. The Court disagreed, holding that "[w]hen several words are followed by a clause which is applicable as much to the first and other words as to the last, the natural construction of the language demands that the clause be read as applicable to all." Id. at 1721 (quotation and citation omitted).

The Paroline court further noted that "[i]t is . . . a familiar canon of statutory construction that [catchall] clauses are to be read as bringing within a statute categories similar in type to those specifically enumerated." Id. This "familiar canon of statutory construction," the associated-words canon, arises when words "are associated in

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[44] The Supreme Court references the surplusage canon of statutory construction, which provides that "[i]f possible, every word and every provision is to be given effect . . . . None should be ignored. None should needlessly be given an interpretation that causes it to duplicate another provision or to have no consequence." ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 174 (1st ed. 2012). Justice Scalia noted that this truism applies to "all sensible writing." See id.

a context suggesting that the words have something in common." SCALIA & GARNER, supra note 44, at 195. These associated words often "involve listings," but a list is by no means a prerequisite. See id. at 197. When applying the associated-words canon, "[the words] should be assigned a permissible meaning that makes them similar." Id. at 195.

A court must begin with "the assumption that the ordinary meaning of the language chosen by Congress accurately expresses the legislative purpose." See Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238 (2011) (internal quotation and citation omitted). The use of a term of art, or a "common-law term," generally carries with it the assumption that "the term . . . comes with a common law meaning, absent anything pointing another way." See id. In addition, "when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it is taken." Air Wisc. Airlines Corp. v. Hoeper, 134 S. Ct. 852, 861-62 (2014). This inquiry will require, as discussed below, a review of a statute's legislative history and the "body of learning" from which the words originated. See id. at 862.

2. Agency guidelines

In the context of patent law, guidelines published by the United States Patent and Trademark Office ("USPTO") are also instructive in interpreting a statute as they provide a practitioner's perspective on a given issue. See, e.g., Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059, 11,075 (Feb. 14, 2013) (to be codified at 37 C.F.R. 1). While the USPTO

guidelines typically serve as a "guide to patent attorneys and patent examiners on procedural matters," a court may take judicial notice of guidelines so long as the USPTO's interpretation does not conflict with the statute. See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1180 n. 10 (Fed. Cir. 1995). It should be noted, however, that these guidelines are not binding on a court. See Enzo Biochem, Inc. v. Gen–Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002).

3. Legislative history

This Court must give effect to congressional intent by "look [ing] not only to the particular statutory language, but to the design of the statute as a whole and to its object and policy." Crandon v. United States, 494 U.S. 152, 158 (1990) (citation omitted). Committee Reports, "which represent the considered and collective understanding" of Congress "in drafting and studying proposed legislation," are crucial when considering an issue of first impression. In re Swanson, 540 F.3d 1368, 1376 (Fed. Cir. 2008) (quotation and citation omitted). Although the Supreme Court has identified the Committee Report as the authoritative source on discerning legislative intent, House and Senate records are also instructive in determining a statute's underlying policy. See Bettcher Indus., 661 F.3d at 646 (using relevant House and Senate records to "confirm" interpretation of § 317 of Patent Act).

Prior versions of statutory provisions may also supply further evidence of congressional intent. See Russello v. United States, 464 U.S. 16, 23 (1983) In Russello, the Supreme Court interpreted a section of the RICO chapter of the Organized Crime Control Act of 1970 by applying the "ordinary meaning of the words used." See id. at 21 (quotation and citation omitted). The Court's interpretation

was bolstered by earlier proposed versions of the legislation, which contained a limiting definition of the word at issue. See id. at 23–24. The Court held that "[w]here Congress includes limiting language in an earlier version of a bill but deletes it prior to enactment, it may be presumed that the limitation was not intended." Id. This principle does not only apply to prior limiting language. When looking to prior versions of legislation, courts should "not assume that Congress intended to enact statutory language that it has earlier discarded in favor of other language." See Chickasaw Nation v. United States, 534 U.S. 84, 93 (2001) (internal quotation and citation omitted).

4. Public policy considerations

The last factor that this Court will consider in interpreting § 102(a)(1) is the public policy underlying the passage of the ALA in its entirety. "[T]he meaning of statutory language, plain or not, depends on context." Holloway v. United States, 526 U.S. 1 (1999). Thus, it is essential to consider the AIA's other amendments and Congress's policy goals in enacting them, as these changes illustrate the overarching statutory scheme. See Bettcher Indus., 661 F.3d at 644 ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme."). The importance of interpreting a statute in the context of the larger statutory scheme is crucial, as "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001).

d. Application of legal standards

The Court will now consider the parties' specific arguments regarding their proposed interpretation of § 102(a)(1) of the AIA.

1. Statutory construction

Plaintiffs assert that the plain language of § 102(a)(1) supports their interpretation that a patent may only be invalidated under the AIA's on-sale bar if the claimed invention was made available to the public prior to its effective filing date. (See dkt. 209 at 19.) They argue that the phrase "otherwise available to the public" is a modifying clause that is "applicable as much to the first and other words as to the last." (See id. at 21 (quotation omitted).)

The United States Court of Appeals for the Federal Circuit ("Federal Circuit"), Plaintiffs claim, has endorsed the same interpretation of modifying clauses. (See id.) In Resource Conservation Group, LLC v. United States, 597 F.3d 1238 (Fed. Cir. 2010), the Federal Circuit held that the theory of last antecedent—wherein qualifying words refer solely to the last antecedent—is "overcome by other factors showing a different meaning." See Res. Conservation Grp., *LLC*, 597 F.3d at 1245. In Finisar Corp. v. DirecTV Grp., Inc., 523 F.3d 1323 (Fed. Cir. 2008), the Federal Circuit held that "when a modifier is set off from a series of antecedents by a comma, the modifier should be read to apply to each of those antecedents." See Finisar Corp., 523 F.3d at 1336–37. Plaintiffs argue that the placement of the modifying clause "otherwise available to the public," bolstered by the Supreme Court and Federal Circuit interpretations of similar clauses, renders the statute's language unambiguous. (See dkt. 209 at 20.)

Defendant sets forth two statutory interpretation arguments in opposition to Plaintiffs: (1) the term "on sale" is a term of art that was left unchanged in the AIA and thus the prior meaning still applies; and (2) "otherwise available to the public" is a disjunctive phrase that is meant to serve as a residual category of publicly available prior art. (See dkt. 226 at 18–21.)

Defendant first argues that "when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it is taken." (See id. at 19 (quotation and citation omitted).) Teva provides the example of the phrase "a patent shall be presumed valid," which the Supreme Court held as requiring a clear and convincing evidence standard. (See id.) See also Microsoft Corp., 131 S. Ct. at 2246. The Supreme Court reasoned that the clear and convincing evidence standard applies "because courts before 1952 had interpreted the presumption in that manner." (See dkt. 226 at 19.) See also In re Nuijten, 500 F.3d 1346 (Fed. Cir. 2007) (concluding that by reenacting "manufacture" as a category of patentable subject matter in 1952, despite other changes to 35 U.S.C. § 101, Congress intended to adopt pre-1952 judicial definitions of the term "manufacture"). Defendant argues that Plaintiffs have not "overcome this presumption." (See dkt. 226 at 20; cf. dkt. 204 at 29 ("If Congress had intended to graft a new 'public' requirement onto the on-sale bar, it could have done so explicitly by adding a 'public' modifier to 'on sale' . . . just as section 102 contains the phrases 'printed publication' and 'public use.'").)

Teva also claims that "otherwise available to the public" constitutes a residual category "to capture invalidating disclosures that do not fall into one of the enumerated

categories in section 102." (See dkt. 226 at 20.) Defendant distinguishes Paroline and Resource Conservation by noting that "[n]othing in Paroline—or in Resource Conservation for that matter—suggests that the addition of a catch-all category to a pre-existing statute could change the established meaning of language retained in the statute." (See id. at 21 (emphasis in original).) Teva also highlights Plaintiffs' failure to cite to any case "where an amendment to include a residual 'or otherwise' clause had the effect of deleting decades of precedent. . . ." (Id.)

Plaintiffs flatly disagree with Defendant's argument that "Congress has left the . . . language [of § 102] virtually unchanged from the original 1836 Act." (See dkt. 226 at 19.) Plaintiffs first point out that "the language surrounding the words 'on sale' did change significantly under the AIA." (See dkt. 236 at 9.) Plaintiffs note that the elimination of geographic limitations, the regrouping of different prior art categories, and the addition of "otherwise available to the public" indicate that § 102(a) was not left "virtually unchanged." (See id.) Plaintiffs add that the Defendant's cases discussing an unchanged words presumption are distinguishable because Congress, in those cases, "amended the statutes to include terms of art." (See id. at 9 n. 3.) Here, Plaintiffs assert, Congress "changed the surrounding language in providing a new legal standard, which it elucidated in the legislative history." (Id. at 9.)

Plaintiffs also argue that the Defendant's argument for a residual category that "has no bearing on the scope of the separate 'on sale' category" requires that the word "otherwise" be interpreted as surplusage, which would violate the surplusage canon of statutory interpretation. (See id. at 8.) See also SCALIA & GARNER, supra note 44, at 174.

2. Agency guidelines

Plaintiffs bolster their statutory interpretation argument by referencing the USPTO's published guidelines on § 102(a). (See dkt. 209 at 20.) Plaintiffs note that the USPTO published guidelines after a comment period and its own statutory interpretation analysis, and concluded that "secret sale or use activity does not qualify as prior art." (See id.) The guidelines define a sale or offer for sale as secret "if, for example, it is among individuals having an obligation of confidentiality to the inventor." (Id. at n. 10 (quotation and citation omitted).) Plaintiffs note that the USPTO instructed that the "relevant inquiry is focused on 'whether the sale . . . made the invention available to the public.'" (Id.)

Teva emphasizes that the USPTO guidelines are nonbinding on this Court. (See dkt. 226 at 33.) See also Enzo Biochem, Inc., 323 F.3d at 964. Defendant notes that the USPTO acknowledges that the guidelines were issued "as a practical matter" until "the courts . . . ultimately address questions concerning the meaning of AIA 35 U.S.C. § 102." (Id. (quotation and citation omitted).) Defendant argues that because the USPTO intended these guidelines only to serve as temporary guidance, the Court need not consider them. (See id.)

Plaintiffs reply that it is significant that the USPTO arrived at the same interpretation of § 102(a)(1) as the Plaintiffs "after a comprehensive study, which included a thorough analysis of the legislative history." (See dkt. 236 at 14.) Plaintiffs note that the USPTO's interpretation of the AIA should not be "downplay[ed]." (See id.)

3. Legislative history

Plaintiffs argue that the legislative history confirms their plain meaning interpretation of § 102(a)(1). (See dkt. 209 at 22.) They note that the Committee Report is "the most persuasive [source] . . . on the bill in question" because it incorporates by reference the Senate hearings in which the AIA's sponsor, Senator Kyl, explained the AIA's on-sale bar. (See id. at 22-24.) Plaintiffs claim that Senator Kyl's statements in these hearings highlight the congressional intent to require that a claimed invention be made available to the public in order for the on-sale bar to apply. (See id. at 23.) Plaintiffs cite the record from the March 8, 2011 Senate hearing in pertinent part: "The word 'otherwise' makes clear that the preceding clauses describe things that are of the same quality or nature as the final clause—that is, although different categories of prior art are listed, all of them are limited to that which makes the invention 'available to the public.'" (Dkt. 236-3 at 16 (Mar. 8, 2011 Congressional Record).) In a September 8, 2011 hearing on the final bill, Senator Kyl stated:

> As Chairman Smith most recently explained in his June 22 remarks, "contrary to current precedent, in order to trigger the bar in new 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date." . . . When the committee included the words "or otherwise available to the public" in section 102(a), the word "otherwise" made clear that the preceding items are things that are of the same quality or nature. As a result, the preceding events and things are limited to those that make the invention "available to the public."

(Id. at 237 (Sept. 8, 2011 Congressional Record).)

Defendant sets forth two arguments in opposition to the Plaintiffs: (1) the AIA is a culmination of Congress's prior attempts to enact patent reform in 2005, 2007, 2008, and 2009—all of which left the on-sale bar unchanged; and (2) Plaintiffs' interpretation of the AIA's legislative history improperly relies on a "minority view." (See dkt. 226 at 22–31.)

Teva notes that attempts were made in 2005 and 2008 to "expressly change [ ] the on-sale bar to exclude non-public sales, and did not pass." (Id. at 23.)[45] Other attempts at patent reform, particularly in 2007 and 2009, retained the "public use" and "on sale" categories of prior art. (See generally id. at 23–27.)[46] Defendant argues that the House's 2007 patent reform bill maintained the on-sale bar because of "how the terms 'in public use' and 'on sale' have been interpreted by the courts" and because "there is nothing inherent in a first-to-file system that will deter inventors from making use of their inventions as trade secrets and then some time later filing a patent application for the invention." (See id. at 24 (citation omitted).) Teva notes that despite the inclusion of the phrase "otherwise available to the public" in the 2007 and 2009 bills, Senator Kyl objected to the 2009 Senate bill because

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[45] The wording of this rejected amendment defined invalidating prior art as that which is "patented, described in a printed publication, or otherwise publically [sic] known." (See dkt. 226 at 23.) The 2008 proposed amendment defined invalidating prior art as that which is "patented, described in a printed publication, or otherwise made available to the public (other than through testing undertaken to reduce the invention to practice)." (See id. at 25 (citation omitted).)

[46] The proposed wording of the 2007 and 2009 amendments defined invalidating prior art as that which is "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public." (See id. at 25–27.)

the bill should have removed any "patent-forfeiture provisions that apply only to non-public prior art." (See id. at 27.) Defendant argues that this objection thus indicates that Senator Kyl was aware that the phrase "otherwise available to the public" still included secret prior art. (See id.)

Plaintiffs state that the Defendant attempts to minimize the sponsoring Senator's statements but "do[es] not cite a single statement from any congressperson that either rebuts the portions of the legislative history that Plaintiffs cite or affirmatively supports their statutory interpretation." (See dkt. 236 at 10.) Plaintiffs also note that Defendant cannot point to any support for its position in the Committee Report, "[d]espite its importance to statutory interpretation . . . ." (See id. at 12.) Plaintiffs claim that Defendant's arguments regarding prior patent reform bills are "based on mischaracterizations . . . and misleading inferences . . . ." (See id.) Plaintiffs clarify that only the 2007 patent reform bill "purpor[ted] to 'maintain' the pre-AIA on-sale bar." (See id. at 13.)

4. Public policy considerations

Plaintiffs argue that the AIA's overhaul of the United States patent system, i.e., converting from a first-to-invent to a first-inventor-to-file system, comports with the policy underlying the changes to the on-sale bar. (See dkt. 209 at 24–25.) Plaintiffs note that under the prior first-to-invent system, "there was a need to prevent an inventor from commercially exploiting the invention substantially beyond the statutory term through first conducting secret sales or offers for sales, and then filing a patent application." (Id. at 25.) Under the first-to-invent system, the on-sale bar deterred "an inventor's attempt to

commercialize his invention beyond the statutory term." (Id. (quotation and citation omitted).) The first-inventor-to-file system, however, adequately incentivizes an inventor to promptly apply for a patent because "the applicant risks having her invention patented by another that may have invented later." (See id. (quotation and citation omitted).)

Defendant critiques Plaintiffs' policy argument, stating that "this narrow view ignores the broader policy principles of the on-sale bar, which continue after the AIA." (See dkt. 226 at 31.) Defendant argues that the on-sale bar still functions as a deterrent for secret commercialization because "there is nothing inherent in a first-to-file system that will deter inventors from making use of their inventions as trade secrets and then some time later filing a patent application for the invention." (See id. at 32.) Defendant notes that Plaintiffs' proposed interpretation of § 102(a)(1), in which commercialization does not "affect[ ] the inventor's right to seek patent protection later," would have the opposite effect of encouraging secrecy. (See id.)

Plaintiffs maintain that the AIA's amendments reflect a significant shift in Congress's prioritization of certain policies underlying patent law. (See dkt. 236 at 14.) Plaintiffs argue, with respect to the Defendant's arguments that the first-inventor-to-file system has no effect on secret commercialization, that the AIA's prior-use defense allows "secret uses of one's proprietary technology." (See id. at 15.) Plaintiffs claim that the expansion of the prior-use defense enables secret uses without "forcing the first inventor to file a patent application" or "risk[ing] infringement under the 'first-inventor-to-file' system." (See id.) Thus, Plaintiffs contend, Congress intended the different provisions of the AIA to function together such that the

on-sale bar now applies only to "publicly accessible" prior art. (See dkt. 236-3 at 84 (AIA Committee Report) ("[T]he phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publicly accessible.").)

The Court, having considered the parties' arguments on the plain language meaning of § 102(a)(1), the USPTO's guidelines, the undisputed AIA Committee Report, and the public policy considerations underlying the passage of the AIA, concludes that § 102(a)(1) requires a public sale or offer for sale of the claimed invention. The new requirement that the on-sale bar apply to public sales comports with the plain language meaning of the amended section, the USPTO's interpretation of the amendment, the AIA Committee Report, and Congress's overarching goal to modernize and streamline the United States patent system. (See dkt. 236-3 at 83–84 (AIA Committee Report).)

2. Findings as to sale or offer to sell pre-AIA

The Court will now make findings on the "sale or offer to sell" prong as to the '724, '725, and '424 patents, which are subject to the pre-AIA on-sale bar. For purposes of the pre-AIA on-sale bar, the Court finds that the MGI Supply Agreement constitutes a sale because it was a contract for a future commercial product. See U.C.C. § 2–105(2) ("purported present sale of future good or of any interest therein operates as a contract to sell"). The fact that the clearly-described "products" had not yet received FDA approval at the time of the contracting does not change this conclusion. See Section II.A.3. Moreover, because the sale was made more than one year prior to the application date of the patents-in-suit, the MGI Agreement satisfies the pre-AIA sale prong under Pfaff. See

Pfaff, 525 U.S. at 67. The Court will now consider whether Helsinn's agreements with Oread and SP ("Oread and SP Agreements") also satisfy the sale prong of the pre-AIA on-sale bar.

a. Applicable legal standards

The Court notes that during the bench trial in this case, the Federal Circuit issued an opinion in Medicines Co. v. Hospira, Inc., 791 F.3d 1368 (Fed.Cir.2015), vacated by Medicines Co. v. Hospira, 805 F.3d 1357 (Fed. Cir. 2015), which addressed the issue of whether a sale for services constitutes a commercial sale under the pre-AIA on-sale bar. See id. at 1371. After closing arguments in this case, the Federal Circuit vacated its opinion in Medicines Co. and granted that plaintiff's petition for rehearing en banc. See Medicines Co., 805 F.3d at 1358. The Court notes that the issue of what constitutes a commercial sale under the pre-AIA on-sale bar remains in flux at this time. See id.

The facts underlying the district court's holding in Medicines Co. arose from ANDA litigation in which the ANDA applicant alleged, inter alia, that the patents-in-suit were invalid under the on-sale bar. See Medicines Co., 791 F.3d at 1370.[47] The Medicines Company hired Ben Venue to prepare batches of bivalirudin, a synthetic peptide used as an anticoagulant, "using an embodiment of the patented method." See id. at 1369. The batches were for both commercial and clinical packaging.

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[47] A summary of the facts of Medicines Co. is provided in this Memorandum Opinion as the parties relied heavily on this case during their closing arguments. (See generally dkt. 353.) The prior ruling in Medicines Co. will be referenced by the Court only in the context of the parties' arguments.

See id. at 1370. The Medicines Company acknowledged that "each batch had a commercial value of over $10 million." See id. at 1371. The ANDA applicant alleged that the claimed invention was commercially offered for sale before the critical date. See id. at 1370. The district court found, inter alia, that the patents-in-suit were not invalid under the on-sale bar because: (1) the patentholder had only contracted with a manufacturing company for the sale of "manufacturing services"; and (2) the developmental batches manufactured under the agreement fell under the experimental use exception of the on-sale bar. See id. At issue on appeal is whether these facts constitute a commercial sale under the pre-AIA on-sale bar.[*]

The facts set forth in Medicines Co. are distinguishable from Trading Technologies International, Inc. v. eSpeed, Inc., 595 F.3d 1340 (Fed. Cir. 2010). In Trading Technologies, an inventor hired Trading Technologies ("TT") to build trading software in accordance with the inventor's idea. See Trading Techs., 595 F.3d at 1361. TT built the customized software and the inventor paid TT for this custom software. See id. The patent challenger ar-

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[*] The Federal Circuit requested briefing on the following issues:

(a) Do the circumstances presented here constitute a commercial sale under the on-sale bar of 35 U.S.C. § 102(b)?

(i) Was there a sale for the purposes of § 102(b) despite the absence of a transfer of title?

(ii) Was the sale commercial in nature for the purposes of § 102(b) or an experimental use?

(b) Should this court overrule or revise the principle in Special Devices, Inc. v. OEA, Inc., 270 F.3d 1353 (Fed.Cir.2001), that there is no "supplier exception" to the on-sale bar of 35 U.S.C. § 102(b)?

Medicines Co., 805 F.3d at 1358.

gued that the inventor's consulting agreement with TT invalidated the patent-in-suit under the on-sale bar. See id. The Federal Circuit held that the parties' consulting agreement was not a sale under the on-sale bar because "TT promised to develop trading software for [the inventor] because he lacked the technical expertise to do so." See id. The court held that "[i]nventors can request another entity's services in developing products embodying the invention without triggering the on-sale bar." Id. The court noted, in so holding, that an inventor's request to manufacture a product for "secret, personal use could not constitute a sale under 35 U.S.C. § 102(b)." See id.

"[A] sale is a contract between parties to give and to pass rights of property for consideration which the buyer pays or promises to pay the seller for the thing bought or sold." Bone Care Int'l, LLC v. Pentech Pharms., Inc., 2012 WL 1068506, at *6 (N.D. Ill. Mar. 29, 2012) (quoting In re Caveney, 761 F.2d 671 (Fed. Cir. 1985)). In Bone Care, the patentholder entered into a supply agreement with a manufacturer to produce batches of vitamin D_2 that the patentholder was "stockpiling for the purposes of commercialization after FDA approval of Bone Care's first NDA." Id. at *6. The court compared these facts to Trading Technologies, emphasizing that the contract "was not for services rendered . . . but explicitly set forth terms related to the sale of goods." Id.

b. Parties' arguments

Helsinn first argues that the Oread and SP Agreements were service contracts, in which Oread and SP provided services like manufacturing, formulation development, and analytical development to Helsinn. (See dkt.

353 at 96.) Helsinn analogizes this case to Trading Technologies, wherein the Federal Circuit held that inventors may request another entity to perform services without violating the on-sale bar. (See id.) See also Trading Techs., 595 F.3d at 1361. Helsinn asserts that its agreements with Oread and SP were similar in that they were for the development of products embodying the '219 patent. (See dkt. 353 at 98.)

Helsinn also argues that the Oread and SP Agreements were for developmental batches of its product, thus falling outside the "commercial sale" scope of the on-sale bar. (See id. at 97.) Helsinn distinguishes Medicines Co., noting that the commercial batches produced in Medicines Co. violated the on-sale bar because "[t]hey were stockpiled," marked with commercial numbers, and ready for shipping in anticipation of a launch. (See id. at 97–98.) Helsinn notes that the Oread and SP Agreements did not contemplate the purchase and sale of commercial batches; rather, the agreements were used "for clinical development, . . . stability testing," and other services "en route to seeking FDA approval." (See id. at 98.) Helsinn emphasizes that a pre-AIA analysis that invalidates patents based upon these developmental supplier agreements carries dangerous public policy implications because:

> Small companies like Helsinn rely extensively on contract manufacturing organizations during the development process of getting a pharmaceutical product to the market . . . . [I]f we are to invalidate patents based on use of CMOs [contract manufacturing organizations], there's going to be an awful lot of pharmaceutical patents that are in trouble out there that were never shown to work for their intended purpose during that developmental phase . . . .

(Id. at 99.)

Teva argues that the Oread and SP Agreements were "clearly binding commercial contracts" because the agreements set forth contractual terms like price and quantity. (See id. at 10–12.) Teva notes that Helsinn's interpretation of the Oread and SP Agreements as service contracts is tantamount to "characteriz [ing] any sale of a product as a service contract." (See id. at 12.) Teva relies upon the Federal Circuit's holding in Medicines Co., although as this Court has noted, the Federal Circuit vacated this opinion after the parties' closing arguments in this case. Teva also notes that Bone Care is instructive in this case as the court held that the supply agreement between the parties "was not for services rendered . . . but explicitly set forth terms related to the sale of goods." *Bone Care*, 2012 WL 1068506, at *6. (See also dkt. 353 at 30.)

With respect to Helsinn's argument that the on-sale bar does not apply to contracts for development batch manufacturing, Teva asserts that Helsinn has "expressly stipulated that they are not asserting the experimental use doctrine." (See dkt. 353 at 21; see also dkt. 317 at 2.) Teva also notes that the on-sale bar does not provide any "carve out for . . . CMOs or development agreements." (See dkt. 353 at 21.) Teva argues that in similar cases where the company did not have the manufacturing ability to develop its own drug product, such as Bone Care and Medicines Co., the courts found that these agreements qualified as "sales" under the on-sale bar. (See id. at 30.)

c. Analysis

The only issue that this Court will address in this subsection is whether the Oread and SP Agreements constitute a commercial sale or offer for sale under the pre-AIA on-sale bar. See 35 U.S.C. § 102(b). The Court, taking into consideration the parties' arguments and the unsettled law in this area, finds that the Oread and SP Agreements are not sales or offers for sale under the pre-AIA on-sale bar.[49]

The nexus of the parties' disagreement lies in whether the stockpiling for development processes like clinical trials one year prior to a patent's critical date constitutes a commercial sale or offer for sale under the on-sale bar. Helsinn argues that contracts that supply a company with its developmental batches for clinical trials and data-gathering cannot be considered a commercial sale or offer for sale. (See, e.g., dkt. 353 at 99.) Teva counters that Helsinn seeks to carve out a novel exception to the on-sale bar, and that "paying to have the product made . . . is starting to convert his invention into something that can be commercialized . . . ." (See id. at 21; id. at 30.)[50]

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[49] The Court agrees with Teva that Helsinn's argument that the Oread and SP Agreements were merely service contracts invites a slippery slope analysis in which this Court declines to engage. (See dkt. 353 at 12 ("[Y]ou could characterize any sale of a product as a service contract.").)

[50] Although not briefed by the parties, the Federal Circuit's rehearing en banc of Medicines Co., particularly on the issue of whether a supplier exception to the on-sale bar exists, may be instructive in these pharmaceutical patent cases with facts analogous to this case or Medicines Co. This Court cannot, however, read the tea leaves on the outcome of the Medicines Co. rehearing and will not do so here.

The sparse case law on this issue is distinguishable in part from this case, although the Court does bear in mind some similarities.[51] Unlike Trading Technologies, Oread and SP Agreements were not entered into for the purpose of Helsinn conducting its own "secret, personal use" of its product. See Trading Techs., 595 F.3d at 1362. But, similar to Trading Technologies, the Court finds that these agreements were not for the commercialization of Helsinn's product. (See dkt. 322 at 125, 129.) Unlike Bone Care, the Oread and SP Agreements were not entered into for the purpose of stockpiling a commercial product while anticipating FDA approval and a commercial launch. See Bone Care, 2012 WL 1068506, at *3. This case is similar to Bone Care in that both Bone Care and Helsinn lacked their own manufacturing capacity, and Helsinn's acknowledgement that the developmental batches were "commercial" in size is comparable to developmental batch "stockpiling." (See dkt. 312 at 19–20.)

The Court reverts back to the Pfaff test, which requires a claimed invention to be the subject of a "commercial offer for sale." See Pfaff, 525 U.S. at 67. There is no dispute that Helsinn and Oread, and later Helsinn and SP, entered into binding contracts for the manufacture of developmental batches of palonosetron, including "commercial scale" batches to satisfy NDA requirements. But the Court finds nothing in these agreements to suggest the contracts contemplated a commercial sale of any of those batches. (See, e.g., dkt. 322 at 125, 129.) Unlike Bone Care, Helsinn was not stockpiling its commercial product, or anticipating a launch with those batches pending FDA approval. See Bone Care, 2012 WL 1068506, at *6 (quotation

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[51] As noted above, the Court is not considering the Federal Circuit's prior ruling in Medicines Co. for purposes of this analysis.

omitted) ("Bone Care was stockpiling for the purposes of commercialization after FDA approval of [its] first NDA."). Rather, Helsinn entered into the Oread and SP Agreements for the purpose of pursuing FDA approval, which includes, as Dr. Calderari testified, "analytical development, formulation development, batches preparation for clinical trials, and stability data generation." (Dkt. 322 at 122.)

The Court also finds compelling Helsinn's argument that many pharmaceutical companies rely upon the outsourcing of developmental batch manufacturing before the commencement of clinical trials. (See dkt. 353 at 99.) While the on-sale bar is intended to prevent the commercial exploitation of a patent prior to its critical date, the Court does not see how supply agreements for developmental batches can reasonably be considered commercial exploitation when, particularly in the pharmaceutical field, the developmental batches are critical to pre-commercialization steps, like clinical trials, formulation development, and manufacturing quality requirements. See, e.g., D.L. Auld Co. v. Chroma Graphics Corp., 714 F.2d 1144, 1147 (Fed. Cir. 1983). (See also dkt. 322 at 122.) In this case, the Court finds a marked difference between the commercial stockpiling in Bone Care and the developmental batches that were manufactured in this case.

The Court finds, for the above-stated reasons, that the Oread and SP Agreements do not constitute sales under the pre-AIA on-sale bar.

3. Findings as to sale or offer to sell post-AIA

As this Court has interpreted the post-AIA on-sale bar, the "sale" prong of the on-sale bar is satisfied by a public sale or offer for sale of the claimed invention. See,

e.g., 35 U.S.C. § 102(a)(1) (barring patentability if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public").

The Court has found in Section II.A.2 that the Oread and SP Agreements were not "sales" under the pre-AIA on-sale bar. The Court further finds that the Oread and SP Agreements were not "public" sales under the post-AIA standard, because they were entirely subject to and performed under confidentiality restrictions. See Sections I.C.4 and I.C.8.

The Court will next consider whether the MGI License Agreement and the MGI Supply Agreement (collectively, "MGI Agreement") satisfies the post-AIA on-sale bar sale prong.

a. Legal standard

An agreement that "relates specifically to [a] supply of . . . worldwide requirements for what are clearly commercial purposes . . . constitutes an offer to sell that has been accepted." Enzo Biochem, Inc. v. Gen–Probe, Inc., 424 F.3d 1276 (Fed. Cir. 2005) ("Supply of worldwide requirements at reasonable times and prices surely means commercial supply . . . ."). In Enzo, the patentholder entered into an agreement that provided, "Enzo shall supply to Ortho and Ortho shall purchase from Enzo for use in Licensed Products no less than ninety percent (90%) of Ortho's United States requirements or seventy-five percent (75%) of Ortho's worldwide requirements of Active Ingredients . . . ." Id. at 1279.

Enzo argued that the agreement was vague and did not require Ortho to purchase the patent's embodiment

exclusively from Enzo. See id. at 1282. The patent challenger alleged that the agreement "created the necessary contractual obligations on the parties to constitute a commercial offer for sale." Id. at 1281. The Federal Circuit held that:

> Enzo's claimed invention, the polynucleotide probe, is a tangible item or product that can be sold or offered for sale. The language of that provision clearly imposes upon Enzo the obligation to sell and on Ortho the obligation to purchase a significant percentage of its U.S. and worldwide requirements of the product labeled "Active Ingredients." There is no doubt that paragraph 2.14 constitutes a binding commitment by the parties to enter into a commercial sale and purchase relationship.

Id.

The Federal Circuit also emphasized that Enzo's emphasis of the context of this particular sale provision was inapposite and "d[id] little to alter the plain language of that provision in the agreement." See id. at 1282.

The determinative factor under the sale prong of the on-sale bar is the contractual language of the agreement. See generally Apotex, Inc. v. Cephalon, Inc., 2011 WL 6090696 (E.D. Pa. 2011). In Apotex, the patentholder entered into a supply and license agreement in which its supplier had the "right to sell modafinil, a pharmaceutically active compound . . . and Cephalon wishes to purchase the Compound from Lafon." Id. at *15. The court found that the agreement's language was analogous to the Enzo agreement in that both provided for a "free supply of product for clinical testing," and "contain[ed] language akin to a requirements contract," including "to purchase"

and "to sell." Id. at *16. The court also noted that any mention of research and development in the contract was "incidental to the primary commercial purpose of the contract . . . ." See id.

Conversely, an agreement may not be considered a sale or offer for sale under the on-sale bar if the agreement lacks material terms that are common to commercial documents. See Elan Corp. v. Andrx Pharms., Inc., 366 F.3d 1336 (Fed. Cir. 2004). In Elan, the patentholder sent letters to various entities stating that Elan was seeking a partner in planning clinical studies. See id. at 1337–38. The letter also discussed granting a license and a pricing structure without any specific price term. Id. at 1341–42. The product at issue in Elan, a formulation of naproxen for the treatment of inflammation and pain, had not yet been patented or received FDA approval at the time of the letters being sent. See id. at 1337. The Federal Circuit concluded that there was no offer for sale in the letters because "an offer to enter into a license under a patent for future sale of the invention covered by the patent when and if it has been developed . . . is not an offer to sell the patented invention that constitutes an on-sale bar." Id. at 1341. The court noted that the letter did not contain "any mention of quantities, time of delivery, place of delivery, or product specifications beyond the general statement that the potential product would be a 500 mg once-daily tablet containing naproxen." Id.

b. Parties' arguments

Helsinn first argues that the on-sale bar does not apply because the MGI Agreement was indefinite as to the product that was going to be manufactured. (See dkt. 353 at 100–01.) The MGI Agreement defined "Products" as

"the pharmaceutical preparations for human use in I.V. dosage form containing the Compound as an active ingredient in the formulation that will be described in the Registration. . . ." (DTX-115-0007.) Helsinn analogizes this case to Elan, arguing that in both cases, the product was unspecified at the time the agreement was formed, and it was unclear as to whether a product actually existed at the time of the alleged offer for sale. (See dkt. 353 at 102.) Helsinn would distinguish Enzo from this case, arguing that "[t]he product at issue in [the Enzo] agreement was real. It was tangible. It was set in concrete." (See id.)

Helsinn next argues that the MGI Agreement never made the claimed invention available to the public prior to the critical date, thus never triggering the on-sale bar. (See dkt. 209 at 29; dkt. 353 at 87–88.) Helsinn argues as a threshold matter that the on-sale bar requires disclosure of the claimed invention, rather than the fact that a sale has merely occurred or will occur. (See dkt. 353 at 88.) Helsinn asserts that in order for a claimed invention to become available to the public and trigger the on-sale bar, the "very specific set of claim limitations" must be disclosed. (See id.)

Here, Helsinn notes that the MGI Agreement was executed in private and contained confidentiality provisions. (See dkt. 209 at 30.) Helsinn argues that its press releases and MGI's Form 8-K filed with the Securities and Exchange Commission were redacted and only contained information that "two parties [we]re working on the palonosetron product." (See dkt. 353 at 88.) Helsinn also emphasizes that the press releases and the Form 8-K failed to "disclose[ ] any aspect of the claimed invention of the '219 patent other than the use of the active ingredient palonosetron, which was already known in the prior art." (See

dkt. 209 at 30.) Helsinn concludes that because the claimed invention itself, i.e., Helsinn's palonosetron formulation, was never made available to the public, the on-sale bar has not been satisfied as it relates to the MGI Agreement. (See id.)

Teva argues that the MGI Agreement constitutes a sale or offer for sale under the on-sale bar. (See dkt. 353 at 18–19.) Teva first argues that the language of the agreement, on its face, requires a finding that the agreement is a requirements contract "that easily satisfies the Pfaff requirement of a 'commercial offer for sale.'" (See dkt. 226 at 35; see also dkt. 353 at 18.) In support of its contention, Teva notes that the MGI Agreement includes contract terms for product, quantity, and price for the "sale of Helsinn's palonosetron product that is an embodiment of the asserted claims of the '219 patent." (See dkt. 226 at 35.)

Teva also asserts that this case is analogous to Enzo insofar as Helsinn argues that the uncertain product defined in the MGI Agreement negates applicability of the on-sale bar. (See dkt. 353 at 19.) Teva notes that the Federal Circuit, in Enzo, summarily dismissed the patentholder's vagueness argument because the contract imposed "upon Enzo the obligation to sell and on Ortho the obligation to purchase . . . ." See Enzo, 424 F.3d at 1282. Teva argues that the language of the MGI Agreement, regardless of the definition of Helsinn's palonosetron product, set forth contractual terms under which both parties were bound. (See dkt. 353 at 18.)

With respect to Helsinn's threshold argument, i.e., that every claim limitation of the claimed invention must be made available to the public for a sale or offer for sale to satisfy the on-sale bar, Teva states that this "is not the

law now, and has never been." (See id. (citation omitted).) Teva argues that even under the post-AIA on-sale bar, the MGI Agreement invalidates the '219 patent because: (1) MGI was a member of the public at the time of the agreement; and (2) MGI's Form 8-K "discloses Helsinn's binding commercial sales agreement with MGI for the palonosetron product." (See dkt. 226 at 39–40.)

Teva first argues that "[t]he Federal Circuit has repeatedly held that for purposes of the on-sale bar, the 'public' is broadly defined and includes an independent party, not controlled by the seller, entering into an arms-length sales agreement for the later-patented good." (Id. (citations omitted).) Teva argues that because MGI is an independent entity and entered into an agreement with Helsinn, the sale was therefore available to the public. (See id. at 39.) Moreover, Teva asserts that MGI's Form 8-K "makes clear" that Helsinn had contracted to supply MGI's requirements for the palonosetron product for a price, so that MGI could in turn resell that product. (See id. at 40.) Teva notes that the "Product" disclosed in the MGI Agreement "embodies each of the asserted claims of the '219 patent," which satisfies the sale prong of the on-sale bar. (See id.)

c. Analysis

The Court is not persuaded by Helsinn's argument that the on-sale bar does not apply because the product defined in the MGI Agreement was indefinite or uncertain because it had not yet received FDA approval. (See dkt. 35[illegible] at 100–02.) The Court is guided by Enzo and Apotex, in which the Federal Circuit held that the sale prong of the on-sale bar is satisfied if an agreement between parties is for a commercial purpose (i.e., a sale or offer for

sale) and contains contractual language. See Enzo, 424 F.3d at 1282; Apotex, 2011 WL 6090696, at *16.

Here, Helsinn and MGI entered into a Supply and Purchase Agreement for the sale of Helsinn's commercial palonosetron product. (See dkt. 226 at 14.) The MGI Supply Agreement contained contractual terms relating to Helsinn's product, the quantity of product that would be sold to MGI, and at which price. (See id. at 35.) It is inapposite that at the time of the agreement, the product was uncertain and awaiting FDA approval, because the appendices to both the MGI License Agreement and the MGI Supply Agreement specified the exact dosages and concentrations that were in the pending FDA filings. See Section I.C.9. (See dkt. 353 at 100–02.) Indeed, under a pre-AIA analysis, the Court's analysis would end here with a conclusion that the MGI Agreement constituted a contract for sale, thus satisfying the "sale" prong of the on-sale bar.

However, the post-AIA on-sale bar also requires that the sale or offer for sale make the claimed invention available to the public. See 35 U.S.C. 102(a)(1) (barring patentability if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention"). It is not sufficient that a sale or offer for sale merely occur.[52]

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[52] This Court is further bolstered by the USPTO's interpretation of the post-AIA on-sale bar, in which the USPTO concluded, "the sale must make the invention available to the public." See Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy–Smith America Invents Act, 78 Fed. Reg. 11,059, 11,075 (Feb. 14, 2013) (to be codified at 37 C.F.R. 1).

The Court finds that the MGI Agreement did not make the claimed invention available to the public. Teva asserts that the Form 8-K and Helsinn's press releases made the existence of the agreement available to the public. (See dkt. 226 at 40–41.) However, MGI's Form 8-K was redacted and indicated only that Helsinn and MGI had entered into an agreement to purchase Helsinn's product. (See, e.g., dkt. 226 at 14.) Additionally, Helsinn's press releases only disclosed the existence of the agreement between Helsinn and MGI. (See id.) Insofar as these documents publicized the parties' MGI Agreement, Teva is correct. But the post-AIA on-sale bar inquiry is not focused on the public disclosure of the sale or offer for sale; rather, the "sale" prong of the on-sale bar requires that the sale make the claimed invention available to the public one year prior to its critical date. Teva has failed to show how MGI's Form 8-K or Helsinn's press releases on the MGI Agreement made Helsinn's claimed invention, i.e., its palonosetron formulation, available to the public. See Section I.A.9.

The Court finds, for the reasons stated above, that the post-AIA on-sale bar does not apply to the MGI Agreement because the sale or offer or sale did not make Helsinn's claimed invention available to the public one year prior to the critical date.

4. Findings on ready for patenting

The Court, having considered the "sale" prong of the on-sale bar under both pre-AIA and post-AIA standards, will now consider whether the patents-in-suit were ready for patenting by the critical date of January 30, 2002. See Pfaff, 525 U.S. at 67–68. The parties agree that the "ready

for patenting" prong under Pfaff has remained unchanged by the AIA. (See dkt. 353 at 37, 119.)

a. Legal standards

In Pfaff, the Supreme Court held that an invention may be ready for patenting in two ways: (1) "proof of reduction to practice before the critical date;" or (2) "by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." See Pfaff, 525 U.S. at 67–68. To demonstrate reduction to practice, a party must prove that the inventor (1) "constructed an embodiment or performed a process that met all the limitations" and (2) "determined that the invention would work for its intended purpose." Z4 Techs., Inc. v. Microsoft Corp., 507 F.3d 1340 (Fed. Cir. 2007).[53] As patents are presumed valid, the patent challenger must prove by clear and convincing evidence that the claimed formulation was ready for patenting at the time of the critical date. See SRAM Corp. v. AD-II Eng'g, Inc., 465 F.3d 1351 (Fed. Cir. 2006).

Whether a claimed formulation has been reduced to practice is a fact-driven analysis that may require an analysis of the parties' claim construction. See, e.g., Mitsubishi Chem. v. Barr Labs., Inc., 435 Fed. Appx. 927, 934–35 (Fed. Cir. 2011); Allergan, Inc. v. Sandoz, Inc., 2011 WL 1599049 (E.D. Tex. Apr. 27, 2011). In Mitsubishi, the district court interpreted the claim "pharmaceutical composition for injection" to mean "a composition that is suitable

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[53] The Court will focus on whether the claimed invention was reduced to practice, i.e., shown to work for its intended purpose, as this was the central issue disputed by the parties. (See, e.g., dkt. 353 at 37; id. at 102.)

for treating medical conditions by injection." Mitsubishi, 435 Fed. Appx. at 934 (quotation omitted). The patent challenger argued on appeal that the claim should have been interpreted as "a medicinal drug composition that can be administered by injection." See id. The patent challenger cited precedent in which the Federal Circuit had construed the term "pharmaceutical" to mean "medicinal drug." See id. (citing to Novartis Pharms. Corp. v. Eon Labs Mfg., Inc., 363 F.3d 1306 (Fed. Cir. 2004)). The court distinguished Mitsubishi from Novartis, noting that the claim limitation at issue in Novartis was a preparation claim and thus did not apply to the composition claim at issue in Mitsubishi. See id. The court further noted that "[c]laims to pharmaceutical compositions are typically distinct from claims to medicinal compounds themselves." See id. (internal quotation omitted). The Federal Circuit affirmed the district court, noting that "[t]he specification does not require this restrictive construction, nor is this property necessary for patentability." Id.

In Allergan, the parties disputed whether the claim construction at issue should include the additional limitation of "with a drug that meets FDA standards for approval." See Allergan, 2011 WL 1599049, at *8. The patent challenger argued that "in the United States, a patient cannot be legally treated with a drug that is not approved by the FDA." Id. The district court found that "it would be improper to read this limitation into the claims," because "FDA approval is irrelevant to proceedings before the [PTO]." See id.; see also AstraZeneca v. Apotex, 633 F.3d 1042 (Fed. Cir. 2010) (noting that, in an induced infringement case, the FDA's opinion regarding a proposed label amendment was inapposite because "the FDA is not the arbiter of patent infringement issues").

In other cases, a factual determination as to whether a formulation was ready for patenting, i.e., reduced to practice, may hinge on the timeline and completion of the formulation's clinical studies. See, e.g., In re Omeprazole Patent Litig., 536 F.3d 1361 (Fed. Cir. 2008) ("The district court found that the claimed formulation was not reduced to practice before the clinical trials were completed, and we uphold that finding."); Estee Lauder Inc. v. L'Oreal, S.A., 129 F.3d 588 (Fed. Cir. 1997) ("[W]hen testing is necessary to establish utility, there must be recognition and appreciation that the tests were successful for reduction to practice to occur."); Bayer Schering Pharma AG v. Barr Labs., Inc., 2008 WL 628592, at *44 (D.N.J. Mar. 3, 2008) ("The extensive clinical testing demonstrates that there was a lack of confidence that the efficacy of the claimed invention could be based solely on the European trials."), aff'd on other grounds, 575 F.3d 1341, 1346 (Fed. Cir. 2009) (stating the "adverse rulings"—concerning the ready-for-patenting prong of the on-sale bar—were not cross-appealed).

In Omeprazole, the claimed formulation that was the subject of the underlying ANDA litigation was created in 1979. See Omeprazole, 536 F.3d at 1372. At that time, the inventors tested various formulations in order to "create a dosage suitable for commercialization," which included Phase II and Phase III trials. See id. at 1372–73. The patent challenger asserted that the patentholder's clinical trials violated the on-sale bar because "it was known in 1979—the year Astra filed its first patent application for omeprazole—that omeprazole could provide a safe and effective treatment." See id. at 1375.

The district court found that the patentholder's Phase III formulation was not reduced to practice because the

inventors had stated that the formulation only "might solve" problems associated with the formulation in earlier clinical trials. See id. at 1373. The district court noted that at the conclusion of Phase III trials, the formulation "still required extensive clinical testing and real-time stability testing to determine whether it could treat gastric acid diseases safely and effectively." Id. at 1373–74. The Federal Circuit affirmed the district court, noting that "[t]he existence of the formulation . . . does not establish that . . . the invention would work for its intended purpose." See id. at 1374–75.

Even if a formulation's clinical trials are fully completed and analyzed, the formulation may not be considered ready for patenting if the completed clinical trials studied a different patient population. See Bayer, 2008 WL 628592, at *43. In Bayer, the patent challenger asserted that the patentholder's claimed invention was invalid because it was in public use, i.e., reduced to practice, during European clinical trials, prior to the patent's critical date. See id. at *13. Unlike the case before this Court, the patentholder maintained that the United States ("U.S.") clinical trial was an experimental use. Id. at *38. Bayer asserted that its U.S. clinical trials were experimental because: (1) it was unknown whether the formula would be effective in the U.S. population; (2) the U.S. subjects were "far more diverse" than the subjects in the European trials; and (3) it was unknown how the test results between U.S. and European trials would differ. See id.

The court noted in its analysis that the European trials found that "both medications were shown to be effective oral contraceptives." Id. at *42. However, Bayer's experts testified that "the U.S. clinical trials were necessary to de-

termine whether the formula would be effective as an ovulation inhibitor in the U.S. population," citing the populations' differences in "weight, smoking/alcohol habits, and ethnic backgrounds." See id. at *43. The court noted that in Omeprazole, there was insufficient evidence of a reduction to practice because at least one clinical trial had not yet been analyzed. See id. The court held that in the present case, the patent challenger had not shown by clear and convincing evidence that the U.S. clinical trials were not necessary to show the formulation's safety and efficacy. See id. at *44. Accordingly, the court found that "[t]he extensive clinical testing demonstrates that there was a lack of confidence that the efficacy of the claimed invention could be based solely on the European trials." Id.

b. Applied legal standards

The Court will first address the parties' legal analyses of the ready for patenting prong of the on-sale bar. The Court will then address the parties' factual arguments as to whether Helsinn's claimed formulation was ready for patenting before the critical date.

1. Parties' arguments

Helsinn argues that its claimed formulation's treatment-like limitation—"to reduce the likelihood of [CINV]"—renders the Omeprazole holding even more applicable to the case before this Court. (See dkt. 353 at 116-17.) Helsinn notes that the limitation at issue in Omeprazole was a "pure formulation claim," which is a "less compelling" case for a court to require completed Phase III clinical testing. (See id.) Unlike Omeprazole, where the parties had full results from one Phase III

study, Helsinn notes that it only had preliminary, unanalyzed Phase III clinical trial results as of January 30, 2002. (See id. at 117.) Helsinn asserts that its treatment limitation makes this a unique case that goes beyond the facts asserted in Omeprazole, and requires fully completed and analyzed Phase III clinical trials to determine whether the invention was effective and ready for patenting. (See id.)

Teva argues that "courts regularly distinguish between patentability and FDA approval." (See id. at 54–55.) In terms of claim construction, Teva highlights Mitsubishi, noting that in that case, the Federal Circuit refrained from equating the term "pharmaceutical" with the FDA classification "safe, effective, and reliable for use in humans." (See id. at 54.) Teva argues that the court so held because FDA approval is irrelevant to a patentability analysis. (See id. at 54–55.)

Teva also argues that Omeprazole is irrelevant because the issue in that case was whether the Phase III formulation was stable. (See id.) Teva notes that Helsinn has stipulated to its claimed formulation's stability, and the only issue on this prong of the on-sale bar is the formulation's efficacy. (See dkt. 317 at 2.) Teva argues that Omeprazole does not address how fully analyzed and completed Phase III clinical trials are instructive to an efficacy analysis. (See dkt. 353 at 55.) Moreover, Teva notes that nowhere in Omeprazole does the Federal Circuit state that "FDA standards must be met before an invention is ready for patenting." (See id. at 56.)

1. Expert opinions

Dr. Fruehauf

Teva presented opinion testimony of Dr. John Fruehauf on the "ready to patent" prong of the on-sale bar issue. Dr. Fruehauf is an M.D. clinical oncologist with a Ph.D. in pharmacology who teaches, conducts clinical trials, and practices oncology at University of California Irvine and its comprehensive cancer center. He was accepted to testify as an expert in the clinical sciences and pharmacology, with a focus on oncology and supportive care. (Dkt. 324 at 4–14.)[54]

Dr. Fruehauf testified that in his opinion, a person of ordinary skill in the clinical sciences would know as of January 30, 2002 that palonosetron administered to a human reduces the likelihood of CINV. (Id. at 30–31.) The key documents that he discussed in support of that opinion he listed as follows:

- the Phase II 2330 study records;
- the July, 1998 Helsinn Clinical Meeting Minutes;
- the November, 1999 proposed Phase III protocols Helsinn sent to the FDA;
- the September, 2000 Helsinn press release announcing the Phase III start;
- the Phase III study documents; and

[54] Each of the experts who appeared in this trial was eminently qualified to provide the testimony they offered. The Court was highly impressed with each of their credentials and explanations of their opinions, and it was an honor and a pleasure to have them at the trial.

- a declaration later filed with the USPTO [not in the same patent family history] addressing invention timing issues ("Cantoreggi declaration").

(Id. at 33–34.)

Addressing the Phase II study 2330 records, Dr. Fruehauf referred to the text and a table in the Final Report of that study dated July 1995, DTX-0227-0005. He said the design of the study was "a very strong design for a Phase II trial." (Dkt. 324 at 36.) He summarized that the basic objective of the study, as stated in the text, was to determine whether palonosetron, over a dose range of 1 to 90 micrograms per kilogram, given to patients receiving highly emetogenic chemotherapy, would reduce the likelihood of CINV. The primary endpoint to be studied was complete control at 24 hours, defined as no nausea and no vomiting. A secondary endpoint studied was called "complete response," meaning no vomiting but some nausea reported. He pointed to the stated conclusion:

> Palonosetron, administered as a single IV injection of 3, 10, 30 or 90 μg/kg . . . was effective in suppressing [CINV] for 24 hours. All four doses were approximately equally effective as compared with the combined results from a cohort of 0.3 and 1 μg/kg.

(Id. at 37.)

Dr. Fruehauf discussed the Complete Control figures in the table presented with that study 2330 conclusion, which is shown here in the margin.[55] He stated that in his opinion, if a person of skill in clinical sciences were to see this Syntex data as of 1995, "it would be clear that the drug at the .25 mg dose [equivalent to 3 mcg/kg in the table] reduced the likelihood of nausea and vomiting." (Id. at 42–44 (bracketed text added).)

He was questioned by counsel for Helsinn about that table, and acknowledged that the "Complete Control" line — the primary endpoint of the study — showed there was no statistically significant difference between results for the bottom doses of 0.3-1 mg and any of the higher doses, including the 3 mcg/kg [0.25 mg] dose, except the 30 mcg/kg [2.1 mg] dose indicated with an asterisk. He said, "[t]hat is correct from a statistical perspective." (Id. at 130–34.) He also confirmed his awareness that in general, the FDA will not allow an indication to be claimed for a drug without a showing of statistical significance of an outcome for the primary efficacy endpoint of a study. (Id.)

He was also asked if he knew that the Syntex Formulation Book, as a result of all the analyses of the Phase II

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Parameters	RS-25259 Dose (μg/kg)				
	0.3-1	3	10	30	90
% Complete Control (24hrs)	24	46	40	50	46
%CompleteResponse (24 hours)	24	39	40	48	46
Median time (hours) to Failure (first emetic episode or rescue Rg)	5.6	22.7	19.0	>24*	21.8*

*statistically significant differences ($p<0.05$) vs. lowest dose group

(DTX-0227-0015.)

studies in May of 1995, recommended a palonosetron dose of 1 milligram for Phase III CINV trials. He said he was not aware of that fact. (Id. at 145–46, citing DTX-0254 and DTX-1023.)

Dr. Fruehauf was also shown the FDA's comments and instructions in the March 10, 1999 meeting with Helsinn, where the FDA said "[d]ue to a lack of dose response in this study, these data are inadequate to serve as pivotal efficacy support," and the FDA allowed Helsinn to re-analyze the 2330 data using historical controls in order to offer it as "supportive data" for efficacy. (Id. at 137–38.) He said in his opinion the FDA made a mistake about that; he said, "I think it [the 2330 study] did have a dose response. I think it was just a misunderstanding on the part of the [FDA] reviewer. . . ." (Id. at 137–38, 198–99 (bracketed text added).)[56] He explained that in his view, because the lowest doses showed low effect (albeit not in statistically significant numbers), and because the next four doses were all equivalent, that was a dose response. (Id. at 198–99.)

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[56] Here the Court notes that a close review of the 1995 Final Report of the 2330 study shows that the subsequent re-analysis resulted in an Errata statement added to that Report after the re-analysis of the data was conducted and reported in the PALO-00-01 Final Report. The Errata statement, dated August 12, 2002, reported that the table shown in the 1995 Final Report of the 2330 study, see n. 55 supra, was actually erroneous because the lines for Complete Control (the primary endpoint) and Complete Response (the secondary endpoint) were reversed. (DTX-0227-0012, -0013.) Thus, looking at the second line of data in the table, which is the actual data for Complete Control according to the Errata, there is not even one statistically significant figure, as shown by the lack of any asterisk in that second line of figures. Of course, Helsinn and the FDA did not know this fact on March 10, 1999 at the "End of Phase II" meeting, or when Helsinn submitted its proposed Phase III protocols dated November 15, 1999.

The next document Dr. Fruehauf discussed in support of his opinion was the July 1998 Helsinn Clinical Meeting Minutes, reflecting the week-long meeting in Palo Alto, CA attended by scientists from Helsinn, the former Syntex, and consultants including Dr. Gandara. See n. 17 supra and accompanying text. There, the outcome of the meeting was to further study doses of 0.25, 0.75 and 2.0 mg, and corresponding concentrations in a 5 ml solution, for possible use in the Phase III trials. (DTX-0015-0008, -0009.)

Dr. Fruehauf interpreted those discussions to indicate that Helsinn at the time regarded the 0.25 dose as the minimum effective dose, "and they were going to take that with a couple of other doses that were higher into the Phase III study." He also said he agreed with Dr. Gandara's recommendation that "3μg/kg was most likely the correct dose for CINV." (Dkt. 324 at 48–49, citing DTX-0015-0008, -0012.) His basis for that opinion was "[b]ecause I think it's clear from the [Phase II] trial that the .25 milligram dose was the inflexion point, and after that you've saturated the receptors and that that's the minimally effective dose, and you want to avoid higher doses because, as you go up on doses, you're more likely to get side effects." (Id. at 50 (bracketed text added).)

On cross-examination, Dr. Fruehauf agreed that the stated outcome of the 1998 Helsinn Clinical Meeting was to keep the 2.0 mg dose in the selected group, and that dose was equivalent to the 30 mcg/kg dose that was shown as the only statistically significant dose in the Phase II 2330 study primary endpoint data. (Id. at 154–55.) He also acknowledged that although he routinely participates in clinical trials in his medical work, he has never been personally involved in the selection of a specific dosage of a

drug in a treatment that was eventually approved by the FDA. (Id. at 111–12.)

Dr. Fruehauf also relied upon his reading of the proposed Phase III protocols that Helsinn submitted to the FDA dated November 15, 1999. (DTX-0293.) He referred to the statement that "[d]ata from [the 2330] study clearly demonstrate that the 3 μg/kg dose of palonosetron is the minimal effective dose in preventing CINV." (DTX-0293-0035 (bracketed text added).) He stated that he agreed with this statement, which was based on the same data shown in the table in the 1995 Final Report (see n. 55 supra). He said that in his opinion, if a person of skill were to see this statement to the FDA, "[t]hey would interpret this statement as to indicate that the Phase II study showed that the .25 milligram dose could reduce the risk of nausea and vomiting." (Dkt. 324 at 55–56.) The version of that 2330 study table contained in the November 1999 Phase III protocols, however, carried forward the same lack of statistical significance for Complete Response for any dose except the 30 mcg/kg, equivalent to 2.0 mg, dose. (See DTX-0293-0034.)

Dr. Fruehauf also cited the Helsinn press release of September 14, 2000, announcing the commencement of the Phase III trials. There, the company said, "[t]he Phase II trials demonstrated the efficacy of Palonosetron in the prevention of emesis with no significant side effects. . . ." (Dkt. 324 at 56–57.) He said that in his view, a person of skill in the art would understand from this statement that Helsinn knew that palonosetron reduced the likelihood of emesis. (Id.)

He also recognized, however, that when the database from the earliest of those trials was unblinded but not fully analyzed at the other end of the Phase III trials in

January 2002, the Helsinn press release on January 16, 2002 said "[w]e are pleased to have completed all patient treatment and to have begun analysis of the data collected in the palonosetron clinical program." That press release said "The Phase 2 clinical trial results were promising, and we are hopeful that the Phase 3 Palonosetron data will demonstrate that it can make a difference for cancer patients suffering from CINV." (Id. at 182–83, citing DTX-0040.)

Dr. Fruehauf next discussed the fact that the "preliminary" data tables for PALO-99-03, dated January 7, 2002, which Helsinn sent to the FDA with its letter of February 7, 2002, turned out to be identical to the corresponding final data tables contained in the Clinical Study Report for that trial dated July 19, 2002. Teva's counsel asked him if it would be surprising that those results in the final report were identical to the preliminary analysis. He replied, "[t]hey have to be because this was the pre-stipulated result of the unblinded data which had been locked so it can't change." (Id. at 65.)

He said that fact supported his opinion "[t]hat we have a clear understanding from a Phase II study that .25 was the minimal effective dose that was carried forward into Phase III, and in the Phase III trial, that .25 milligram dose was very effective at reducing the likelihood of CINV in a prospective randomized trial. . . . Prospective is you plan it in advance, and you do what you plan to do, and you can't change what you plan to do." (Id.) He did not deny, however, that as of January 7, 2002, the figures Helsinn had in hand were preliminary figures only. (Id. at 66.)

The last document relied upon by Dr. Fruehauf for his opinions was a declaration filed by Helsinn in the USPTO on Sept. 2, 2010, in support of a patent application that

was not part of the same patent family history as the patents-in-suit, but it did relate to a proposed method of treatment claim for acute and delayed CINV using a 0.25 mg dose of palonosetron. The first declarant listed was Helsinn executive Sergio Cantoreggi, and the other two declarants were company owners Enrico and Riccardo Braglia. (DTX-0287-0413 ("Cantoreggi declaration").) It stated that Alberto Macciocchi, who was the project manager for the PALO-99-03 study, was then deceased, and the purpose of the declaration was "to establish that Alberto Macciocchi, Enrico Braglia and Riccardo Braglia had conceived the idea to use palonosetron for the treatment of acute and delayed-onset CINV, and had conducted clinical trials in humans to test this idea, at least as early as October 2, 2001." (Id.)

Referring to the Clinical Study Report for PALO-99-03 dated July 19, 2002, attached to the declaration as Exhibit A, the Cantoreggi declaration stated, inter alia:

> 2) We submit this declaration to establish that Alberto Macciocchi, Enrico Braglia, and Riccardo Braglia had conceived the invention defined by claim 1 of this application, and reduced it to practice, before November 16, 2001, the date that Dr. Piraccini published abstract no. 5169 in Blood, vol. 98, no. 11 part 2.
>
> 3) In particular, we submit this declaration to establish that Alberto Macciocchi, Enrico Braglia, and Riccardo Braglia had conceived the idea to use palonosetron for the treatment of acute and delayed-onset CINV, and had conducted clinical trials in humans to test this idea, at least as early as October 2, 2001.
>
> . . . .

> 17) Thus, we had conceived the idea to use 0.25 mg. palonosetron for the treatment of acute and delayed-onset CINV, as described in claim 1, at least as early as August 1, 2001 (the date that the study began).
>
> 18) Most important, we had successfully tested the method in human patients, and we had done so before October 2, 2001 (the date the study was completed).
>
> 19) As reported on page 8 of Exhibit A,
>
> "Pairwise testing revealed differences between palonosetron 0.25 mg and ondansetron in favor of palonosetron 0.25 mg. for . . . number of emetic episodes on Study Days 1, 2, 3 and the time period 0 to 120 hours . . ."

(DTX-0287-0413, -0415.)

Dr. Fruehauf testified that his reading of this declaration indicates that Helsinn was saying that "they knew the result, they knew that .25 milligrams was effective to reduce the risk of chemotherapy-induced nausea and vomiting, by October 2nd, 2001." (Dkt. 324 at 71.) The reference to October 2, 2001 is, of course, the "last patient out" date, as stated on the first page of the Clinical Study Report for PALO-99-03 dated July 19, 2002, which was attached to the declaration as Exhibit A. (See DTX-0287-0418.) Dr. Fruehauf opined that in his experience, saying that they had "successfully tested the method in humans . . . before October 2, 2001," would mean "that they had some understanding from the result of the study and that it was successful." (Dkt. 324 at 72.)

He gave his theory about how Helsinn could have asked the CRO conducting the clinical trial to do some calculations of broad averages in the blinded data before that "last patient out" date, stating that a person of ordinary skill could do the same calculations if they had access to the data. (Id.) On cross-examination, he said he himself did not know what "reduced to practice" meant in the declaration because it is a legal term, so he would not know how those declarants interpreted that term. (Id. at 157–58.) He also said that his theory about Helsinn possibly having obtained broad efficacy information about the blinded data prior to the "last patient out" date of October 2, 2001 was not supported by any evidence and was just his speculation. (Id. at 164–65.)

Dr. Fruehauf further testified that the inactive excipients in the Phase III formula would not impact the efficacy of the 0.25 mg dose when administered to a patient. Therefore, he said, if a person of ordinary skill in the clinical sciences understood that the Phase II formulation with 0.25 mg was effective for CINV, he or she would expect the Phase III formulation to behave in a similar fashion. (Id. at 84.)

The ultimate opinion expressed by Dr. Fruehauf was stated as follows:

> I think it would be clear to a person of skill in the clinical arts, based on the Syntex Phase II study, [and] based on unblinded data analysis of PALO-99-03 where that output was January 7th, and Cantoreggi's declaration that would potentially rely on blinded data, that it was clear that the .25 milligram dose reduced the likelihood of chemotherapy-induced nausea and vomiting.

(Id. at 89 (bracketed text added).)

Dr. Fruehauf also stated that he disagreed with the opinions stated by Helsinn's expert, Dr. Peck, to the effect that one would need two prospective randomized blinded trials, fully analyzed, to know that the 0.25 mg dose reduced the risk of CINV as claimed in the '219 patent. He said he considered FDA criteria and Patent Office criteria to be different. He again stated that in his opinion, on the strength of the Phase II study as confirmed in the first Phase III study, it was clear that the 0.25 mg dose was effective for that purpose. (Id. at 93.)

Dr. Peck

Helsinn presented opinion testimony of Dr. Carl Peck on the "ready to patent" prong of the on-sale bar issue. Dr. Peck is an M.D. with board certifications in internal medicine and in clinical pharmacology who also had a Fulbright fellowship in physical chemistry and a research fellowship in clinical pharmacology focused on pharmacokinetics and biostatistics and involving clinical trials. For many years he was in the U.S. Army, practicing medicine and researching and teaching. That service included founding the division of clinical pharmacology at the Uniformed Services University of Health Services, a military medical school in Washington, D.C.

He was next recruited to become the director of the FDA Center for Drug Evaluation and Research, CDER, where he served for six years and was personally involved in reviewing numerous INDs and NDAs.[57] Next he went

[57] While serving as director of CDER, Dr. Peck was also named Assistant Surgeon General of the United States. (Dkt. 337 at 11.)

to Georgetown University as a professor of pharmacology, founding the Center for Drug Development Science and consulting with companies. He is currently consulting and is designated as a "special government employee" available to consult with the FDA. He was accepted to testify as an expert in scientific standards regarding determinations of the efficacy and safety of pharmaceutical drug products. (Dkt. 337 at 4–16).[58]

Dr. Peck testified with reference to the asserted limitations of the patents-in-suit claiming a formulation intended for IV administration to a human to reduce the likelihood of CINV. He stated that in his opinion, a POSA in the relevant time period would require "fully analyzed results of two adequate and well controlled Phase III studies" in order to determine that a drug formulation would be effective for reducing the likelihood of CINV. (Id. at 22.) It was further his opinion that the pharmaceutical formulations relevant to the patents-in-suit "were not known to work for their intended purpose of reducing the likelihood of CINV in human patients" before January 30, 2002. (Id. at 78.)

Dr. Peck gave three reasons for his opinions. First, the results of a single Phase III trial would not be sufficient for a POSA to know that the drug was efficacious. Second, assuming that the results of a single Phase III were sufficient, the preliminary results from such a study would provide only insufficient information. Third, under the "impossible hypothetical" that Phase III trials were not needed in this case, the Phase II 2330 study as reported

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[58] Teva did not object to Dr. Peck being admitted to testify as offered, but did express a relevance issue with his testimony. (Dkt. 337 at 20.)

"provided only a signal," and the FDA itself said it was insufficient as a pivotal trial, so that would also not be sufficient to convince a POSA of efficacy. (Id.) He added that a pharmaceutical formulation could not be used for IV administration to a human to reduce the likelihood of CINV without FDA approval, except under an active FDA-approved IND. (Id. at 24.)

He stated that the standards he employed were scientific standards that he thinks a POSA (as defined by plaintiffs) would embrace. He explained that "[t]hese are standards that have been developed by a consensus of scientists over many decades. Since FDA is a science-based agency and . . . uses science all the time in its review and guidance and decisions," he referred to FDA standards in forming his opinions in this case. (Id. at 24.) He testified that the FDA is very highly regarded as a scientific and regulatory agency, stating, "I think scientists in the industry and scientists in the academic community recognize that those standards are their standards." (Id. at 26–27.)

Dr. Peck testified that with regard to clinical trials, the FDA sets the standards, and it provides guidance. Importantly, he said, it has "articulated a statistical framework for being able to really know from the data, particularly data that's highly variable, that a drug is working." (Id. at 26.)

Addressing Dr. Fruehauf's reliance on Phase II data in his opinion testimony, Dr. Peck commented that "Phase II studies, with a few exceptions, are never capable of permitting a POSA to really know that the drug will be effective in the broad range of patients that will be candidates for the drug if and when the drug is actually approved." (Id. at 33.) He explained the reasons included that those studies are typically small, they are often very limited in

the type of patients, and they often produce confusing results. (Id. at 33–34.)

Contrasting the purpose and structure of Phase II trials with that of Phase III trials, Dr. Peck described Phase III trials as follows:

> [T]he basic standard for knowing that a drug will work, and one that you can generalize to all patients that would be candidates in the future, are the Phase III trials. These are defined as adequate and well controlled, meaning they're large. They're structured with sound statistical principles. There is a wide range of patients . . . so that they are representative. And they're positioned, also, to provide a much richer collection of data that will be important to the prescriber and to the patient that can be articulated in the prescribing information, the so-called drug label.

(Id. at 34.)

He also explained the reason why two Phase III trials are generally necessary to know whether a pharmaceutical product would work for its intended purpose, which is replication. "[S]cientists always know that one experiment is not necessarily reproducible . . . . [T]he basic, good science requires replication. So you need at least two." (Id.) He said that 40 to 60 percent of Phase II trials that advance to Phase III do not result in approved drugs because one or more of the trials will fail. (Id.) He added that a typical Phase III program in 2003 and at present, as illustrated by the Phase III trials in this case, are done in different centers by different investigators around the world, so there is independence in the replication design.

He said that a drug such as palonosetron would not qualify for a single Phase III trial to get FDA approval. (Id. at 37.)

Dr. Peck reviewed the same Phase II 2330 study documents on which Dr. Fruehauf had testified. Looking at the Final Report of that study dated July 1995, Dr. Peck testified that this was one of five Phase II studies. He said it was "an exploratory dose-ranging study . . . . And the purpose of this was to evaluate graded doses to evaluate the safety and to identify a possible signal of benefit." (Id. at 39–40.) He noted that it was a small study; most of the patients were male and none had received a chemotherapeutic agent before; and "that was quite unrepresentative of any broader population." (Id.)

Looking at the data in the summary table of the 2330 Final Report, see n. 55 supra, Dr. Peck did point out that in the entire table there were only two findings of statistical significance, and both of them were at the 30 mcg/kg level. He also stated that there was no "ordered dose response," because even the stated results for 3 to 90 mcg/kg were 46, 40, 50, and 46. He was asked whether that could indicate that an efficacy plateau was reached at the 3 mg/kg [0.25 mg] level, and he said that was only one hypothesis that could arise from that raw data. Indeed, he said, in the other Phase II studies that were done, the best dose was one of the others. (Id. at 40–44.)

Focusing on the difference in results between the 24% figure for the lowest +. 3 to 1 mcg/kg dose and the 46% result for the 3 mcg/kg dose, he said that might or might not indicate efficacy, stating, "[t]he scientific method, the agreed-upon approach in drug studies, is to couple an apparent difference with a statistically significant difference so that if you were to repeat this trial, you would get the

same result . . . . I really can't conclude anything from the 24 versus 46 because this could change in the next study. It's too small a study." (Id. at 44–45.)

Dr. Peck also reviewed the minutes of the March 10, 1999 meeting of Helsinn with the FDA. He stated that the names of FDA representatives included the CDER division director, the medical team leader, and the medical officer (primary reviewer on the product) – all of whom were M.D.'s, as well as two pharmacologists and a chemist. He chaired many such meetings himself, he said, and has been to many more since leaving his CDER director position in 1993. (Id. at 52.)

He highlighted the various portions of those minutes where the FDA communicated that the Phase II 2330 study data "did not show a convincing dose-response pattern." As he characterized that discussion at the meeting:

> FDA says, well, look, first of all, there's a lack of dose response in that study, so, therefore, we really can't entertain that data set, as is, to support. However, there is a possibility—and this is implied in the future, there is a possibility—that the data itself may be useful as supportive data. So, this is basically a "no," that study is insufficient.

(Id. at 55.)

He also reviewed the re-analysis report of the 2330 study data that the FDA permitted Helsinn to use as support for its pivotal Phase III study PALO-99-05, PTX-182. He said it was a lengthy report that made adjustments to the data, then constructed an "historical placebo" comparator [the study itself was not designed with a placebo], and did a statistical analysis of all that data. "And with those

adjustments," he said, "it turns out that the +.25 milligram and the +.75 . . . both of them were statistically significantly different from this historical placebo, which permitted then the revised data, and analysis, to be viewed by FDA to be adequate to support the already available Phase III trial [referring to PALO-99-05, the HEC trial] that had demonstrated effectiveness." He noted the date of that re-analysis report in August 2002, well after the critical date of January 30, 2002. (Id. at 57–60 (bracketed text added).)

Addressing Helsinn's April 7, 2000 letter to the FDA submitting the November 15, 1999 proposed protocols for the three Phase III studies, Dr. Peck highlighted the contents in those documents where Helsinn said the Phase II results "suggested" efficacy, and that the Phase III trials were designed "to support the hypotheses" that palonosetron was not inferior to existing setrons. He said, "the key word here is 'hypothesis'. We don't know. If they knew, they would have filed a new drug application. They know that more studies have to be done and they're requesting permission to undertake three new . . . Phase III studies." (Id. at 49.)

Dr. Peck described the three full-scale Phase III trials as all using an historical placebo control model, as well as two different comparators (ondansetron and dolasetron), and large numbers of patients at different centers. He said those were "three adequate and well-controlled Phase III clinical trials." Only the first of those three, the PALO-99-03 study, was unblinded before January 30, 2002. (Id. at 60–69.)

The sequence of events after the "last patient out" date of October 2, 2001, reflected in the Clinical Study Report for PALO-99-03, was reviewed and explained by Dr.

Peck. See Section I.C.10. In response to Dr. Fruehauf's discussion of the Cantoreggi declaration and his "hypothetical" analysis of the pre-October 2, 2001 blinded data theorized by Dr. Fruehauf, Dr. Peck said he thought it would be impossible to try to guess what the efficacy outcomes were, even if the sponsor could get access to the data; nor were there any such requests reflected in the study records. (Id. at 69–70.)

Dr. Pecks's explanation of the major analytical process necessary, according to the PALO-99-03 protocols, before and after the "unblinding date" of January 2, 2002, is described above in Section I.C.10.

Referring to the Helsinn letter of February 7, 2002, transmitting to the FDA "the preliminary data for Complete Response," Dr. Peck said "the author of that letter knew exactly what he was saying. This is preliminary. This is not final. And we're just showing you a couple tables." (Id. at 76.)

Dr. Peck said that the tables attached to that February 7, 2002 Helsinn letter to the FDA were one of probably 300 tables that were under analysis at the time, and the table is expressly represented as preliminary data. He said that to evaluate the data reliably, one would need all of the supporting information and more statistical data, as was done for the final Clinical Study Report dated July 19, 2002. He said that although there is no indication that the raw data of the study was changed after the "locked" date, there was at least one amendment to the statistical analysis plan on December 13, 2001. (Id. at 165–66.)

He also did not agree with Dr. Fruehauf that there were no potential differences in the Phase II and Phase III efficacy results based on the different formulations

used in those studies, referring to the saline-based solution in Phase II and the full pharmaceutical formulation in Phase III. He said the buffers differed in their constituents, and the pH was different in the two sets of studies. "So these are fundamentally different formulations," according to him. (Id. at 46.)

3. Analysis

Proof that a claimed formulation has been reduced to practice requires clear and convincing evidence that the inventor (1) constructed an embodiment that met all the limitations, and (2) determined that the invention would work for its intended purpose. Z4 Techs., Inc., 507 F.3d at 1352. Whether the formulation claimed in the patents-in-suit in this case was reduced to practice hinges on the timeline of testing and the knowledge that a person of ordinary skill would have developed in light of the historical facts. Id.

Here, the issue is whether such person would likely know that the claimed intravenous pharmaceutical formulation containing palonosetron was effective for reducing the likelihood of emesis or CINV in a human as of the critical date of January 30, 2002. The Court finds that there is not clear and convincing evidence to establish this prong of the on-sale bar test for patent invalidity. Taking in order the documents relied upon by Teva and its expert on this point, the Court makes the following factual findings. Citations to all the testimony and exhibits on these points are contained in the preceding sections of this opinion. We will use the fixed dose measure in this discussion, e.g., 0.25 mg, rather than the weight-based measure, e.g., 3 mcg/kg, shown in some of the records.

The Phase II 2330 study data, as reported in the Final Report of that study dated July 1995, showed no statistical significance in the stated primary endpoint of Complete Control for 24 hours for any dosage below 2 mg. While the 2330 study was a well-designed Phase II study for its purpose, it lacked the scope and controls that would make it a valid prediction of efficacy at any dose. The FDA so informed Helsinn at the March 10, 1999 "End of Phase II" meeting, and the Court finds that was a scientifically valid observation that a POSA would make when viewing that documentation. Syntex, which presided over all four of the completed Phase II palonosetron trials, ended its research by recommending in its Formulation Book that Phase III use a 1.0 mg dose for CINV.[59]

When Helsinn took over the palonosetron development project and assembled its project team of scientists, and advisors, they struggled long and hard to predict a possible minimum effective dose to take to Phase III trials. Even the highly respected clinician Dr. Gandara, who consulted at the week-long Helsinn Clinical Meeting in July 1998, could only posit that he thought 0.25 mg was "most likely" the correct dose for CINV. He was far superior to being an person of ordinary skill in the art, but that is how he viewed the problem at that time.

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[59] The Court finds further verification that the Final Report of the 2330 study was not as reliable as it would need to be in the fact, not brought out in the evidence at trial, that the very table that summarized the primary endpoint data was wrong and mixed up the results of the primary and secondary endpoints—a fact that was only discovered in the intensive re-analysis study PALO-00-01 suggested by the FDA. See n. 56 supra.

All present at that July 1999 Helsinn Clinical Meeting recognized that Phase III testing was essential to determine the efficacy and correct dosage of palonosetron in a completed pharmaceutical formulation for CINV. The fact that the outcome of that meeting in 1998 was a decision to continue to consider doses of 0.25, 0.75 and 2.0 is also a reflection of the uncertainty, in their view, of the results that might be obtained in Phase III. As Dr. Calderari also testified, even when he and Dr. Macciocchi continued debating the tradeoff between dosage and likely stability, Dr. Macciocchi still wanted to include a much higher dosage than 0.25 or 0.75 in Phase III.

The November 1999 proposed Phase III protocols, submitted to the FDA on April 7, 2000, made numerous statements of hopeful expectation about the 0.25 and 0.75 doses proposed for the trials. Nevertheless, the fact that Helsinn elected to test the two doses, including 0.75 mg, even though it would be a more cumbersome and expensive endeavor, reflected Helsinn's concern that it had no assurance of the efficacy at the 0.25 level. Helsinn was aware, as it stated there, that its "hypotheses" were to be tested in Phase III. Helsinn's statement in the same document that it was "clear" that 0.25 was the minimum effective dose was just one among many less confident statements in the proposal. Likewise, Helsinn's press release statement, at the start of patient enrollment for the trials, that "the Phase II trials demonstrated the efficacy" of the drug was in the nature of a marketing piece rather than any statement of scientific knowledge. Again, in context, the fact that Phase III trials were commencing meant that Helsinn had no such knowledge at that time.

This Court is also not persuaded that the "preliminary" unblinded data of the earliest Phase III study,

PALO-99-03, shown in the three tables dated January 7, 2002, sent to the FDA on February 7, 2002, informed Helsinn or a POSA that the 0.25 mg dose was effective for CINV, which was the only kind of emesis that was even studied at the Phase III level. Those tables were generated a mere five days after the Phase III data was "unblinded," and less than three weeks after the data was "locked" on December 19, 2001. More than six months of additional analytical work lay ahead at that time, leading to the final Clinical Study Report dated July 19, 2002. Indeed, there had already been one amendment to the statistical design of the study on December 13, 2001, and more amendments to the analytical process were entirely possible in the months to follow.[60]

The fact that the summary tables of preliminary data dated January 7, 2002 did not undergo change in their contents during that analytical period, and that data was the same in the final Clinical Study Report as of July 19, 2002, does not in the view of the Court establish that the preliminary results were final. Quite the contrary; it would seem that in view of the changes in methodology that were entirely possible during the analytical period (as experts on both sides agreed), a POSA would not have been surprised at all to see those values change between the preliminary and the final numbers. The Helsinn press release on January 16, 2002 was consistent with that understanding, saying, "[w]e are pleased to have completed all patient treatment and to have begun analysis of the data." See n. 36 supra.

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[60] Another indicator of the fluidity of the analytical process during that period, although not addressed by the witnesses at trial, is seen in the section of the PALO-99-03 Clinical Study Report entitled "Additional changes after unblinding," quoted in n. 38 supra.

The Cantoreggi declaration did state factual truth, based on the historical evidence that the declarants were reconstructing for that PTO submission. It was in an unrelated patent family history, but the Court has carefully considered its content as relevant to the "ready to patent" issue here. The factual content of that declaration states that "we had conceived the idea to use 0.25 mg. palonosetron for the treatment of acute and delayed-onset CINV . . . as least as early as August 1, 2001 (the date that the study [PALO-99-03] began)." "[W]e had successfully tested the method in human patients, and we had done so before October 2, 2001 (the date the study was completed)." (DTX-0287-0415 (bracketed text added).) Both of those facts were literally true. But there is no evidence in this record that Helsinn knew or could have known, until the results of the study were processed, locked, unblinded, and fully analyzed, that those results were successful, nor did the declarants so state. As for the declaration statement that the invention had been "reduced to practice" before November 16, 2001, that was not a statement of historical fact but a use of legal language to support an ultimate factual conclusion at best, and is not binding upon this Court in analyzing the factual issues here.

Teva's expert, Dr. Fruehauf, opined that the results of the Phase II 2330 study, coupled with the preliminary results of the Phase III PALO-99-03 study, were sufficient to have informed a POSA that palonosetron was effective to reduce the likelihood of CINV (which is emesis, as claimed in the first three patents-in-suit), and also that the 0.25 dose of palonosetron was effective to reduce the risk of CINV as claimed in the '219 patent. This Court does not find that the evidence supports such a finding under the clear and convincing standard of proof that applies to this determination.

It is not necessary for the Court to make a further ruling as to whether, as Dr. Peck opined, fully analyzed results of two adequate and controlled Phase III studies were necessary in this particular case to establish the efficacy of the claimed palonosetron formulation. The date when the action stopped, for purposes of the on-sale bar in this case, was January 30, 2002. At that time there were no fully analyzed Phase III studies in this case. Further, as the Court has found, the Phase II data would have been wholly insufficient at that time to support any valid scientific knowledge of efficacy as claimed. Accordingly, for the reasons stated here, and based on all other historical facts described in Section I.C, the Court finds that the patent challenger has not shown by clear and convincing evidence that as of January 30, 2002, the inventor had determined that the invention would work for its intended purpose.

5. Conclusions as to on-sale bar claims

The Court has made the following findings and conclusions in this section, all directed to Teva's claim that the patents-in-suit are invalid under the on-sale bar provision of 35 U.S.C. § 102.

- The MGI Agreement was a "sale" under the pre-AIA. See Section II.A.2.
- The Oread and SP Agreements were not "sales or offers to sell" under the pre-AIA. See Section II.A.2.
- The MGI Agreement was not a "sale" under the AIA. See Section II.A.3.
- Defendant has not shown by clear and convincing evidence that as of January 30, 2002, the inventor had

determined that the invention would work for its intended purpose. See Section II.A.4.

B. Written Description

1. Legal standards

A patent must contain "a written description of the invention." 35 U.S.C. § 112(a). "[T]he hallmark of written description is disclosure." Alcon Research Ltd. v. Barr Labs., 745 F.3d 1180, 1190 (Fed. Cir. 2014). The disclosure must "allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." Enzo Biochem, Inc., 323 F.3d at 968. The disclosure need not contain "either examples or an actual reduction to practice"; rather, the critical inquiry is whether the patentee has provided a description that "in a definite way identifies the claimed invention" in sufficient detail that a person of ordinary skill would understand that the inventor was in possession of it at the time of filing. Alcon Research, 745 F.3d at 1190–91. This is an objective inquiry "into the four corners of the specification." Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010). "A claim that recites a property that is necessarily inherent in a formulation that is adequately described is not invalid as lacking written description merely because the property itself is not explicitly described." Allergan v. Sandoz, Inc., 796 F.3d 1293, 1309 (Fed. Cir. 2015).

A patent is presumed valid, and this presumption can be overcome only by facts supported by clear and convincing evidence to the contrary. Enzo Biochem. Inc., 323 F.3d at 962.

2. Findings and conclusions on written description

Teva asserts that if the Court finds that fully complete Phase III data would be required as claim support in order for the '219 patent to be "ready for patenting" under the on-sale bar, then that patent is invalid for lack of written description because there is no Phase III data, or for that matter any preclinical or clinical efficacy data, in the specification. (Dkt. 312 at 34–35.)

Helsinn argues that the '219 patent specification does satisfy the written description requirement in that it does describe the claimed inventions, both as to formula and as to efficacy. Helsinn cites the formula embodiment described in the specification, "the palonosetron is supplied in vials that comprise 5 ml. of solution, which equate to about 0.25 mg of palonosetron at a concentration of about 0.05 mg/ml." (DTX-0268, col. 10, lines 7–8; see dkt. 311 at 39.) The efficacy information described in the specification is further cited on this point:

> Recently, clinical investigations have been made concerning palonosetron, a new 5-HT3 receptor antagonist reported in U.S. Pat. No. 5,202,333. These investigations have shown that the drug is an order of magnitude more potent than most existing 5-HT3 receptor antagonists, has a surprising half-life of about 40 hours, and is effective to reduce delayed-onset nausea induced by chemotherapeutic agents.
>
> (DTX-0268, col. 1, lines 43–54; see dkt. 311 at 39–40.)

A second point emphasized by Helsinn is that the on-sale bar "ready for patenting" prong is measured on the date one year prior to the patent application filing date,

whereas written description information includes that intervening year and what a POSA would know from publicly available data as of the application date. (Dkt. 320 at 102.) Here, it is undisputed that between January 30, 2002 and January 30, 2003, there was at least one public disclosure of details about the clinical efficacy of the 0.25 mg dose. The PALO-99-04 study results were summarized, in an abstract presented by Helsinn's Dr. Macciocchi and researchers who worked on that trial, at a conference of the Multinational Association of Supportive Care in Cancer ("MASCC") on June 23–26, 2002 in Boston. (PTX-297.) See Section I.C.11.[61] Teva's expert Dr. Fruehauf agreed that the data shown in that Grunberg abstract supports the stated conclusion of the authors. (Dkt. 324 at 124–29.)

Finally, Helsinn argues that the Allergan decision "slammed the door" on the written description defense as asserted here, as the Federal Circuit held that a claim that recites a property that is necessarily inherent in the formulation is not invalid for lack of written description, even if such property is not "explicitly described." (Dkt. 353 at 152.)

The Court finds that the specification of the '219 patent provides an adequate written description of the efficacy of the invention claimed. See 35 U.S.C. § 112(a). The specification discloses the claimed formulations, and the Court finds that as of the provisional application date of

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[61] The parties also agree that the published prior art in this case is defined under 35 U.S.C. § 102(b), so the operative date for published prior art relevant to obviousness is January 30, 2002, which is one year before the priority date of January 30, 2003. (Dkt. 328 at 240–41.) This published reference in June 2002 would not therefore qualify as § 102(b) prior art, but is relevant to what a POSA would know, for purposes of written description analysis, on January 30, 2003.

January 30, 2003, a skilled artisan "would immediately discern the claimed formulation in that disclosure." Moreover, actual data from the PALO-99-04 Clinical Study was publicized by Helsinn at the MASCC conference in June 2002. The Court is also persuaded by Allergan, which held that a property inherent to a claimed formulation is not lacking a written description merely because the property is not "explicitly described" in the specification. Id. Rather, the critical inquiry is whether the formulation itself is adequately described. See id.

Here, the Court is satisfied that Helsinn's claim for a palonosetron formulation "to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting" is adequately supported by the written description in the specification. The Court finds that this description, especially in view of the June 2002 public disclosure, is adequate such that a skilled artisan would have knowledge that the inventors were in possession of the invention at the time of the patent application, and that there is no clear and convincing evidence to the contrary.

C. Infringement

1. Legal standards

Section 271(e)(2)(A) of the Patent Act provides that:

> It shall be an act of infringement to submit—(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . .

35 U.S.C. § 271(e)(2)(A).

Under the Hatch-Waxman framework, the filing of an ANDA constitutes an artificial act of infringement for purposes of creating case or controversy jurisdiction. Ferring B.V. v. Watson Labs., Inc.-Fl., 764 F.3d 1401, 1408 (Fed. Cir. 2014) ("Ferring II"); see also Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990). This artificial, or technical, act of infringement does not in and of itself constitute a literal infringement. See Ferring II, 764 F.3d at 1408 ("The district court here thus erred to the extent that it read § 271(e) to mean that [defendant's] act of filing an ANDA, by itself, established infringement . . . ."). Indeed, once jurisdiction has been established by way of § 271(e)(2)'s technical act of infringement, "traditional patent law principles" control and a court must conduct a traditional infringement analysis. See id. This analysis requires a "comparison of the asserted patent claims against the product that is likely to be sold following ANDA approval . . . ." See id. Moreover, it requires the patentholder to prove the infringement of the asserted patent claims by a preponderance of the evidence. See Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1567 (Fed. Cir. 1997) ("The plain language of the statute does not alter a patentee's burden of proving infringement, nor does it mandate an infringement analysis limited to the scope of the approval sought."). As will be discussed below, a court's analysis differs based upon whether the ANDA specification directly resolves the infringement question or is silent as to the infringement of asserted patent claims.

"[I]f a product that an ANDA applicant is asking the FDA to approve for sale falls within the scope of an issued patent, a judgment of infringement must necessarily ensue." Sunovion Pharms., Inc. v Teva Pharms., USA, Inc., 731 F.3d 1271, 1278 (Fed. Cir. 2013). In Sunovion, the

ANDA applicant requested approval of an amount of stereoisomer ranging from 0.0 to 0.6%. See id. at 1274–75. The patentholder argued that the ANDA specifications infringed its patent, which claimed a stereoisomer of "less than 0.25%." See id. at 1274. The Federal Circuit noted that while the filing of an ANDA itself "constitutes a technical infringement for jurisdictional purposes," a traditional infringement analysis is required to determine whether a court should enter a judgment of infringement. See id. at 1278. The Sunovion court looked to the ANDA specifications, as this was the "subject matter that determines whether infringement will occur." See id. The court held that the ANDA applicant's request for approval for an isomer amount of 0.0 to 0.6% fell squarely within the scope of the "less than 0.25%" limitation set forth in the asserted patent claims and entered a judgment of infringement. See id.

Conversely, "[i]f any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." See Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1247 (Fed. Cir. 2000). The asserted patent claims at issue in Bayer involved a pharmaceutical composition with a specific surface area ("SSA") of 1.0 to 4m^2/g. See id. at 1246. The ANDA applicant requested approval from the FDA of a bioequivalent product with a SSA of 5m^2/g or greater. See id.[62] The court noted that "[t]he focus under § 271(e)(2)(A), is on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred." See id. at 1248 (quotation and citation omitted). "[T]his hypothetical inquiry is

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[62] The district court had also noted that the ANDA applicant's supplier did not sell the composition with a SSA under 4.7m^2/g in the United States. See Bayer, 212 F.3d at 1246.

properly grounded in the ANDA application and the extensive materials typically submitted in its support." See id. However, if the ANDA applicant requests approval of a "well-defined compound, then the ultimate question of infringement is usually straightforward." Id. at 1249. The Federal Circuit reasoned that because the applicant's ANDA specification included a compound which "cannot have a SSA of less than $5m^2/g$ . . . [the applicant] cannot literally infringe the '446 patent." See id.

"In cases in which the ANDA specification does not resolve the infringement question in the first instance, [the Federal Circuit has] endorsed the district court's reference to relevant evidence, including biobatch data and actual samples of the proposed generic composition that the ANDA filer had submitted to the FDA." Ferring II, 764 F.3d at 1409 (citing Glaxo, 110 F.3d at 1567); see also Ferring B.V. v. Watson Labs., Inc.-Fl., 764 F.3d 1382, 1387–88 (Fed. Cir. 2014) ("Ferring I") ("When an ANDA is silent with respect to infringement . . . the correct analysis is under Glaxo . . . , not Sunovion.").

In Glaxo, an ANDA applicant filed for approval of a crystalline compound ("Form 1"). See Glaxo, 110 F.3d at 1564. The ANDA also specified that "the marketed product [would] be approximately 99% pure Form 1 [of the compound]." See id. The patentholder for a different crystalline form ("Form 2") brought suit under § 271(e)(2), alleging that the ANDA applicant infringed its Form 2 patent claim. See id. The ANDA application did not explicitly address what amount of Form 2, if any, would be present in the approved product. See id. at 1566 (internal quotation omitted) ("The [district] court also found that the . . . evidence before it demonstrated in clear and con-

vincing fashion that Novopharm's product would not contain any Form 2 RHC1 and thus would not infringe . . . [the patents].").

The court acknowledged that because the "crystalline compound was capable of existing in multiple crystalline forms, or mixtures thereof, the ultimate question of infringement is not so simple." See id. at 1569. In its analysis, the court reiterated that "the statute [§ 271(e)(2)(A)] requires an infringement inquiry focused on what is likely to be sold following FDA approval." Id. at 1568. When the ANDA specifications do not directly resolve this inquiry, then all relevant evidence, including materials that the applicant submitted to the FDA, as well as the ANDA itself, should be considered by the court. See id. at 1568–70. The court noted that these materials include "actual samples" and "extensive technical data required by the FDA." See id. at 1569 n. 2. The Federal Circuit affirmed the district court's finding that the patentholder had failed to prove infringement by a preponderance of the evidence and noted that the court "properly considered the ANDA itself, the materials submitted by Novopharm to the FDA, and other pertinent evidence provided by the parties." See id. at 1570.

2. Findings and conclusions on infringement

a. Parties' arguments

Plaintiffs argue that there is "no genuine dispute that the CINV dosage strength in Defendants' respective ANDAs literally meets all of the limitations of the asserted claims of the '219 patent." (Dkt. 207 at 12.) Plaintiffs assert specifically that: (1) this Court should interpret § 271(e)(2)(A) as a substantive infringement test for Hatch-Waxman cases, as well as a jurisdiction-conferring

statute; (2) their position on ANDA infringement is supported by current Federal Circuit precedent; (3) Teva fails to cite any authority in support of its non-infringement position; and (4) Teva's characterization of the different dosage strengths as different products is inapposite to the infringement inquiry under § 271(e)(2)(A). (See, e.g., dkt. 207; dkt. 225; dkt. 237; dkt. 353 at 89–90.)

Plaintiffs argue as a threshold matter that § 271(e)(2)(A) is more than a "subject matter conferring statute" and should be interpreted as "the substantive test for infringement in these Hatch-Waxman Act cases." (Dkt. 353 at 90.) Plaintiffs assert that under AstraZeneca v. Apotex, 669 F.3d 1370 (Fed. Cir. 2012), the Federal Circuit held that § 271(e)(2)(A) "establishe[s] a specialized new cause of action for patent infringement." (Dkt. 207 at 12 (quotation and citation omitted).) This new cause of action "directs our analysis to the scope of approval sought in the ANDA." (Id. (quotation and citation omitted).) Plaintiffs argue that under AstraZeneca, "seemingly there should be no dispute here" because Teva has filed an ANDA requesting approval to sell a product in the CINV dosage strength. (Dkt. 353 at 90; see also dkt. 207 at 13–14.)

Plaintiffs next assert that their position is supported by current Federal Circuit precedent. (See dkt. 237 at 5.) Plaintiffs analogize this case to Sunovion, asserting that Teva's ANDA for the CINV dosage strength alone "satisfies the limitations of the asserted claims . . . regardless of whether approval is also sought for other dosage strengths of that product." (See dkt. 207 at 13.) Plaintiffs note that the Federal Circuit found that the ANDA applicant in Sunovion had infringed even though the applicant requested approval for isomers that fell outside of the

"less than 0.25%" asserted patent claim (i.e., 0.26% to 0.6%.) (See id.) Plaintiffs state that "[t]his is analogous to the two dose/volume values that are possible based upon the amount of otherwise identical 0.05 mg/mL palonosetron solution poured into the vials for each dosage strength." (Dkt. 237 at 6.) Plaintiffs distinguish this case from the Glaxo/Ferring line of cases, wherein the ANDA is silent as to the issue of infringement, and note that "if Defendants' approach were correct, then [the ANDA applicant in Sunovion] would have been permitted to sell the 0.3-0.6% isomers . . . ." (See dkt. 225 at 9.)

Plaintiffs also argue that Teva has failed to cite to any authority in support of a finding of non-infringement of the '219 patent. (See dkt. 237 at 10.) Plaintiffs assert that Teva's citation of Ferring I and Ferring II as support for the application of a Glaxo analysis (i.e., looking to the product likely to be sold following ANDA approval) in this case, is misplaced. (See id. at 7–8.) Plaintiffs note that Ferring I and Ferring II clarified that the ANDA specification is central to any infringement analysis, and that a Glaxo analysis applies only when an ANDA is silent as to the asserted patent claims. (See id.)

Plaintiffs further argue that Teva's characterization of the CINV dosage strength and PONV dosage strength as different products is "immaterial, as it cannot be disputed that each of Defendants' ANDAs contains only one ANDA specification defining the scope of approval sought from the FDA." (Dkt. 225 at 5.)[63] Plaintiffs also note that Teva

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[63] Plaintiffs asserted in their opposition memorandum that Teva amended its ANDA to remove the PONV dosage strength "i.e., the entire basis for its summary judgment motion." (See dkt. 225 at 6.)

"do[es] not even address the fact that they can remove the CINV dosage strength from their respective ANDAs, if desired." (See dkt. 237 at 9.)

Teva argues that (1) its PONV dosage strength does not meet "each and every limitation of the asserted claims;" and (2) that Plaintiffs have failed to show by a preponderance of the evidence that Teva's PONV dosage strength product infringes the '219 patent. (See dkt. 202 at 11; dkt. 234 at 7–8.)

Teva first argues that its PONV dosage strength does not meet "each and every limitation of the asserted claims." (Dkt. 202 at 11.) Plaintiffs' asserted patent claims "require a formulation that includes palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base." (Id. at 12 (quotation omitted).) Teva notes that its PONV dosage strength includes a total drug content of only 0.075 mg of palonosetron hydrochloride based on the weight of its free base. (See id.) Teva asserts that "[a]s a matter of law, 0.075 mg cannot be equivalent to 0.25 mg." (Id. (citation omitted).) Moreover, Teva points out that the asserted patent claims require a formulation that has a 5 ml sterile aqueous isotonic solution, whereas Teva's 0.075 mg/1.5 ml product has a solution volume of only 1.5 ml. (See id.) Lastly, Teva notes that Plaintiffs' intended use language is "to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting." (Id. at 13.)

Teva, in reply, denies amending its ANDA to remove the PONV dosage strength. (See dkt. 234 at 5–6.) Teva states that it has "always sought, and continues to seek, final marketing approval from the FDA for this product." (Id. at 6.) The Court will not address this argument as Teva has maintained that it did not amend its ANDA.

Teva argues that its PONV dosage strength product is labeled for the treatment of postoperative nausea and vomiting, and "thus cannot be equivalent." (See id.)

Teva asserts that Plaintiffs have failed to prove, by a preponderance of the evidence, that the PONV dosage strength product infringes the asserted claims under the '219 patent. (See dkt. 234 at 7–9.) Teva argues that Plaintiffs misconstrued the holding in Sunovion, noting that "the Sunovion court used the ANDA specification to define the product on which to base the infringement inquiry." (Id. at 8.) Teva emphasizes that its ANDA specification defines the product—0.075 mg/1.5 ml—and that "there is no question that the 0.075 mg/1.5 ml product, as described in Teva's ANDA, does not meet the limitations of the '219 patent." (See id. at 9.)

Teva further distinguishes *AstraZeneca* by noting that regardless of whether the Federal Circuit established a substantive test for infringement under § 271(e)(2)(A), the court nevertheless held that the patentholder failed to establish, by a preponderance of the evidence, that the ANDA applicant had infringed the asserted patent claims. (See dkt. 221 at 12.) Teva noted that AstraZeneca did not change the Federal Circuit's holding in Glaxo that § 271(e)(2) "does not alter a patentee's burden of proving infringement." (See id. (citing Glaxo, 110 F.3d at 1567).)

b. Analysis

The Court, having considered the parties' arguments, finds that Plaintiffs have not established by a preponderance of the evidence that Teva's 0.075 mg/1.5 ml product infringes the asserted claims of the '219 patent under § 271(e)(2)(A).

Plaintiffs argue as a threshold matter that § 271(e)(2)(A) not only establishes subject matter jurisdiction, but also sets forth the substantive test for infringement under Hatch-Waxman Act litigation. (See dkt. 353 at 89–90; see also dkt. 207 at 13.) Plaintiffs state that the Federal Circuit followed this very approach in AstraZeneca, in which the court held that § 271(e)(2)(A) "establishe[s] a specialized new cause of action for patent infringement." (See dkt. 207 at 12 (quotation and citation omitted).) In that case, the Federal Circuit agreed with AstraZeneca's jurisdictional interpretation of § 271(e)(2), but specifically held that "[w]hile the district court erroneously concluded that it lacked subject matter jurisdiction over AstraZeneca's claims, its judgment of dismissal was nevertheless correct, for we agree with the district court's underlying determination that AstraZeneca failed to state a viable claim for relief under § 271(e)(2)." AstraZeneca, 669 F.3d at 1377.

The Court finds that the holding in AstraZeneca does not overrule the Glaxo holding, i.e., that the infringement inquiry under § 271(e)(2)(A) "is the same as it is in any other infringement suit, viz., whether the patent in question is invalid or will not be infringed by the manufacture, use, or sale of the drug for which the [ANDA] is submitted." Glaxo, 110 F.3d at 1569 (quotation and citation omitted). Moreover, the burden to prove infringement remains squarely on the patentholder. See id. at 1567.

These principles are not limited to those Glaxo-like cases where the ANDA specifications do not resolve the infringement question. Rather, the Federal Circuit has applied this § 271(e)(2)(A) traditional infringement analysis regardless of whether the ANDA specification resolves the infringement inquiry. See, e.g., Ferring II, 764

F.3d at 1408 ("As we have explained, once jurisdiction is established, the ultimate infringement inquiry provoked by [an ANDA] filing is focused on a comparison of the asserted patent claims against the product that is likely to be sold . . . . "); Bayer, 212 F.3d at 1249 ("[T]he focus of the infringement inquiry under . . . § 271(e)(2)(A) is on the product that will be sold after the FDA's approval of the ANDA . . . . "). This Court will thus analyze Plaintiffs' § 271(e)(2)(A) infringement allegations under a traditional infringement analysis.

Here, Teva concedes that its 0.25 mg/5 ml CINV dosage strength product meets the limitations of the asserted claims of the '219 patent. (See dkt. 234 at 9.) However, this does not end the infringement inquiry. (See dkt. 353 at 90.) The Federal Circuit has instructed that the inquiry must focus on "a comparison of the asserted patent claims against the product that is likely to be sold." See, e.g., Ferring II, 764 F.3d at 1408. As Teva has already conceded that its CINV dosage strength product infringes the '219 patent, and leaving aside for the moment the parties' invalidity issues as to all four patents-in-suit, the only product that Teva is likely to sell is the PONV dosage strength. (See dkt. 234 at 9.) Thus, Plaintiffs must prove by a preponderance of the evidence that the PONV dosage strength product infringes the asserted '219 patent claims. See Glaxo, 110 F.3d at 1567.

Plaintiffs argue that there is "no genuine dispute that the CINV dosage strength in Defendants' respective ANDAs literally meets all of the limitations of the asserted claims of the '219 patent." (Dkt. 207 at 12.) While Plaintiffs analogize this case to Sunovion in that both applicants' ANDAs specify an infringing product, this case differs in that "Teva's ANDA specification also defines another

product—the 0.075 mg/1.5 mL product." (See dkt. 234 at 9.) See also Sunovion, 731 F.3d at 1279 (quotation and citation omitted) ("[A]n ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry."). Regardless of whether Teva conceded that one of its two proposed generic drugs infringed the '219 patent, the burden remains with Plaintiffs to prove that the remaining product in Teva's ANDA specification—the PONV dosage strength product—infringed the '219 patent by a preponderance of the evidence. Plaintiffs have failed to do so.

The Court, for the reasons stated above, finds that Teva's PONV dosage strength product (i.e., its 0.075 mg / 1.5 ml product) does not infringe the asserted claims of the '219 patent.

D. Defining the Person of Ordinary Skill in the Art

The obviousness analysis is conducted from the perspective of a person of ordinary skill in the prior art ("POSA"). 35 U.S.C. § 103(a). The same POSA features in the legal standards for the "ready to patent" prong of the on-sale bar under 35 U.S.C. § 102(a), and for written description under 35 U.S.C. § 112. See Sections II.A.4 and II.B.1. The Court is defining POSA here as it relates to the entire patent dispute.

The hypothetical person of ordinary skill "is presumed to be aware of all the pertinent art" at the time the invention was made. AstraZeneca Pharms. LP v. Anchen Pharms., Inc., Nos. 10–1835, 10–4203, 10–4205, 10–4971, 10–5519, 11–2483, 11–2484 (consolidated), 2012 WL 1065458, at *19 (D.N.J. Mar. 29, 2012) (citation omitted).

The person of ordinary skill "is also a person of ordinary creativity, not an automaton." KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007).

The POSA may be a composite of various types of individuals. See AstraZeneca Pharms., 2012 WL 1065458. At issue in AstraZeneca was the validity of a patent covering: (1) sustained release formulations of quetiapine, a compound useful as an antipsychotic agent; and (2) treatment methods that included "[a] method of treating psychotic states or hyperactivity in a warm-blooded animal which comprises administering to said . . . animal an effective amount of a formulation of [any one] of [the] claims." The AstraZeneca court defined the person of ordinary skill as a "clinician or an antipsychotic drug researcher," and a "formulation scientist." Each composite of the POSA took into account the educational level of the inventor and an active worker in the field, as well as the types of problems and solutions encountered in the art, the rapidity of innovation, and sophistication of the technology.

1. Expert testimony

Plaintiffs' expert Dr. Gordon Amidon testified at trial that he would define a POSA as an individual comprising the various facets of a "drug development team" including a pharmaceutical scientist, clinician, and formulation scientist. (See dkt. 342 at 147–48, 152 (sealed).) Dr. Amidon explained that a POSA composed of different fields was necessary because of the interdisciplinary nature of drug development. (See id. at 152.) He explained that a pharmaceutical scientist is necessary for the "physical chemistry and preformulation science" involved in drug development. (Id. at 153.) A clinician is required to establish "clinical parameters," i.e., the dose and the efficacy of the drug.

(Id. at 157.) Dr. Amidon also testified that while a formulation scientist would be involved throughout the entire drug development process, it is the formulation scientist's expertise that ensures a stable product and addresses any manufacturing issues that may arise towards the end of a drug development project. (Id. at 158–59.)

Dr. Amidon's testimony also touched upon the educational qualifications of a POSA. (See dkt. 342 at 148.) He testified that a POSA would have a degree in a chemistry-related field ("pharmaceutical chemistry," "pharmacy," "medicine," "clinical pharmacology," or "general pharmaceutical science") with a B.S., M.S., Ph.D., or M.D. The POSA, by way of incorporating the skill set of a pharmaceutical scientist, would have a knowledge of statistics as well. (See dkt. 342 at 147–48.)

Teva's expert, Dr. Lee Kirsch, proposed a hypothetical POSA as "a formulation scientist typically with a Ph.D. in pharmaceutics or a related field and would have a couple of years of experience in developing I.V. formulations." (Dkt. 326 at 19.) Dr. Kirsch also testified that a POSA would "collaborate with others of ordinary skill in the art" and would "draw upon the knowledge and expertise of clinicians and pharmacologists . . . . " (Id. at 20.)

2. Analysis

The parties do not seem to dispute that a POSA would have an advanced degree in a chemistry-related field, or alternatively, a bachelor's degree with a greater number of years of relevant experience. (Compare dkt. 342 at 148 (requiring "two, three, four years" of relevant experience "depending on the level of education"), with dkt. 326 at 19 (testifying that POSA would typically possess a Ph.D. in pharmaceutics or a related field and have "a couple of

years of experience" in developing I.V. formulations).) The parties also do not dispute that the POSA would include a formulation scientist. (See dkt. 326 at 19; dkt. 342 at 152.)

However, the parties disagree about whether the POSA also should include the knowledge and skills of a clinician or a pharmaceutical scientist, or whether it suffices that the formulation scientist "collaborates" with these individuals. (See id.) Helsinn contends that the POSA would take into account the interdisciplinary nature of drug development and would include both a clinician and pharmaceutical scientist into the POSA definition; Teva argues that the POSA is limited to the formulation scientist. (See id.)

We find merit in Plaintiffs' contention that the person of ordinary skill in the art would possess all the attributes of a multi-member drug development team. The '219 patent is not limited to formulation, but rather includes treatment-like methods as the Court has construed it. (See DTX-0268, col. 10, lines 1–38; dkt. 290.) The parties have stipulated to a similar construction of the claim preambles of the '724, '725, and '424 patents. (Dkt. 290 at 12.) Thus, the "pertinent art" of these patents includes the field of pharmaceutical science, i.e., selecting the API and using the physical chemistry of the API to match it to a delivery system, formulation, or dosage form; the field of clinical medicine, i.e., establishing the dosing, volume, safety, and efficacy of the drug product; and the field of formulation pharmaceuticals, i.e., creating stable formulations of the active pharmaceutical ingredient in preparation for manufacturing. (See dkt. 342 at 134–36, 152–59.)

Dr. Amidon's testimony on defining the POSA encompasses this entire drug development process and his hypothetical POSA included the various professionals and skill sets that are required during this process. (See id.) Conversely, Dr. Kirsch's hypothetical POSA did not consider crucial parts of the drug development process, such as selecting an API or dosage forms. (See dkt. 353 at 128.) As Helsinn argued at trial, Teva's POSA analysis runs afoul of Insite, wherein the Federal Circuit cautioned against an "overly narrow statement of the problem," as this can become a "prohibited reliance on hindsight." Insite Vision Inc. v. Sandoz, Inc., 783 F.3d 853, 859 (Fed. Cir. 2015). (See also dkt. 353 at 128.) Here, Dr. Kirsch's hypothetical POSA "is assigned a particular formulation problem" with issues such as "choosing active ingredients or dosage forms" already decided. (See id. at 128.)

Accordingly, the Court finds that a person of ordinary skill in the art pertinent to the '219 patent would include a pharmaceutical scientist, clinician, and formulation scientist. The pharmaceutical scientist and formulation scientist would have two to four years of relevant experience in their field, as well as an advanced degree in a chemistry-related field, discussed supra. The clinician would have experience in "the therapeutic area" that is the focus of the API, or in this case, treating humans affected by cancer chemotherapy-induced nausea and vomiting. (See dkt. 342 at 134.)

CONCLUSION

This Supplemental Opinion constitutes the Court's further findings of fact and conclusions of law, pursuant to Federal Rule of Civil Procedure 52(a), on the issues ad-

dressed in this opinion. This Supplemental Opinion supersedes the Memorandum Opinion filed here on November 13, 2015 (dkt. 360) only as to the rulings set forth herein. All other rulings set forth in the Memorandum Opinion filed on November 13, 2015 remain in full force and effect.

Based upon the evidence and the findings in this Supplemental Opinion, the Court concludes, under the standard of proof applicable on each of the following issues, that:

(1) Teva proved that the MGI Agreement was a "sale" under pre-AIA;

(2) Teva did not prove that the Oread and SP Agreements were "sales or offers for sale" under pre-AIA;

(3) Teva did not prove that the MGI Agreement was a "sale" under the AIA;

(4) Teva did not prove that the claimed invention of the asserted claims of the '724, '725, '424, or '219 patent was "ready for patenting" as of January 30, 2002;

(5) Therefore, Teva did not prove that the '724, '725 and '424 patents are invalid under the pre-AIA on-sale bar;

(6) Teva did not prove that the '219 patent is invalid under the post-AIA on-sale bar;

(7) Teva did not prove that the specification of the '219 patent fails to provide adequate

written description under 35 U.S.C. § 112(a);

(8) Assuming that the '724, '725, and '424 patents are valid, as the Court has found, the Court agrees with the parties' stipulation that both the 0.075 mg dose and the 0.25 mg dose generic product specified in Teva's ANDA will infringe those three patents;

(9) Assuming that the '219 patent is valid, as the Court has found, the Court agrees with the parties' stipulation that the 0.25 mg dose generic product specified in Teva's ANDA will infringe the '219 patent; and

(10) Assuming that the '219 patent is valid, as the Court has found, the Court further finds that plaintiffs did not prove that the 0.075 mg dose generic product specified in Teva's ANDA will infringe the '219 patent.

This unsealed Supplemental Opinion supersedes the sealed version filed on February 29, 2016 (dkt. 378), which has been vacated by an order filed on this date.

s/Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: March 3, 2016

APPENDIX D

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

No. 11-3962 (MLC) (DEA) (Consolidated)

HELSINN HEALTHCARE S.A. and
ROCHE PALO ALTO LLC,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC. and TEVA
PHARMACEUTICAL INDUSTRIES, LTD.,

Defendants.

November 13, 2015

FINAL JUDGMENT

COOPER, District Judge.
ARPERT, Magistrate Judge.

WHEREAS, Plaintiffs Helsinn Healthcare S.A. and Roche Palo Alto LLC (collectively, "Plaintiffs") asserted that the submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 090713 by Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. (collectively, "Teva") for its generic palonosetron hydrochloride intavenous solution products (0.25

mg / 5 mL and 0.075 mg / 1.5 mL) ("Teva's ANDA Products") infringed U.S. Patent Nos. 7,947,724 ("the '724 patent"), 7,947,725 ("the '725 patent"), 7,960,424 ("the '424 patent"), and 8,598,219 ("the '219 patent");

WHEREAS, Plaintiffs further asserted that the commercial manufacture, use, offer to sell, sale, or importation of Teva's ANDA Products, if approved by the FDA prior to the expiration of the '724, '725, '424, and '219 patents, including any pediatric exclusivity, would infringe the '724, '725, '424, and '219 patents;

WHEREAS, Plaintiffs asserted claims 2 and 9 of the '724 patent, claim 2 of the '725 patent, claim 6 of the '424 patent, and claims 1, 2, and 6 of the '219 patent ("the asserted claims") against Teva.

WHEREAS, this action was tried before the Court on June 2-5, 8-12, 15-16, 2015, and August 12, 2015;

NOW THEREFORE, IT IS ORDERED AND ADJUDGED that for the reasons set forth in the November 13, 2015 Memorandum Opinion, and any further opinion that the Court will issue:

1. Judgment is entered as follows:

a. The asserted claims of the '724, '725, and '424 patents are valid and are infringed by both of Teva's proposed 0.25 mg / 5 mL and 0.075 mg / 1.5 mL generic products.

b. The asserted claims of the '219 patent are valid and are infringed by Teva's proposed 0.25 mg / 5 mL generic product.

c. The asserted claims of the '219 patent are valid and are not infringed by Teva's proposed 0.075 / 1 .5 mL mg generic product.

2. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any final approval of ANDA No. 090713 by the FDA shall be no earlier than July 30, 2024, the expiration of the '724, '725, '424, and '219 patents, including pediatric exclusivity. If Plaintiffs become entitled to any other exclusivities that are not referenced herein, Plaintiffs may apply to the Court for further relief as may be appropriate.

3. Pursuant to 35 U.S.C. § 271(e)(4)(B), Teva and its officers, agents, servants, employees, and attorneys, and other persons who are in active concert or participation with Teva, its officers, agents, servants, employees, and attorneys, are hereby enjoined until the expiration of the '724, '725, '424, and '219 patents, including any applicable exclusivity, from the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any palonosetron hydrochloride intravenous solution product that is the subject of ANDA No. 090713.

SO ORDERED this 16th day of November, 2015.

/s/ Mary L. Cooper
The Honorable Mary L. Cooper
United States District Judge

APPENDIX E

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

No. 11-3962 (MLC)

HELSINN HEALTHCARE S.A., et al.,

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, LTD., et al.,

Defendants.

November 13, 2015

MEMORANDUM OPINION

COOPER, District Judge.

This is an action arising under the Hatch–Waxman Act, 35 U.S.C. § 271(e)(2)(A). Plaintiffs, Helsinn Healthcare S.A. ("Helsinn") and Roche Palo Alto LLC ("Roche") (collectively, "plaintiffs"), are assignees of U.S. Patents No. 7,947,724 ("'724 patent"), No. 7,947,725 ("'725 patent"), No. 7,960,424 ("'424 patent"), and No. 8,598,219 ("'219 patent"). The four patents-in-suit are listed in the FDA "Orange Book" as covering plaintiffs' product

Aloxi®, which is a pharmaceutical composition containing the active ingredient palonosetron. The version of Aloxi® currently marketed by plaintiffs is an intravenous solution with approved indications for preventing or treating cancer chemotherapy-induced nausea and vomiting.

Plaintiffs brought this action, and related consolidated actions, against generic drug manufacturers, Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc. ("DRL"), Sandoz, Inc. ("Sandoz"), Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. ("Teva"). Plaintiffs alleged that each group of defendants had filed an Abbreviated New Drug Application ("ANDA") containing so-called "Paragraph IV" certifications asserting that the claims of the patents-in-suit were invalid and/or not infringed. The asserted claims are claims 2 and 9 of the '724 patent, claim 2 of the '725 patent, claim 6 of the '424 patent, and claims 1, 2, and 6 of the '219 patent. The pertinent limitations of the first three patents are "reducing emesis . . . ," the "0.05 mg/mL" concentration, and "EDTA." The pertinent limitations of the '219 patent are "reduce . . . cancer chemotherapy-induced nausea and vomiting," "0.25 mg" dose in "5 mL . . . solution," and "EDTA."

Defendant Sandoz was dismissed from the action by consent, on December 31, 2014. (Dkt. 247.)[1] The Court issued a memorandum opinion construing certain preamble

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[1] The Court will cite to the documents filed in this case in the Electronic Case Filing System ("ECF") by referring to their docket entry numbers by the designation of "dkt." References to docketed materials are to their ECF pagination. The two later-filed actions that have been consolidated into this lead case are Civil Actions No. 11-5579 and

language in the '219 patent claims, on April 22, 2015. (Dkt. 290.) An 11–day bench trial was conducted in June, 2015, with closing arguments presented on August 12, 2015. (Dkts. 320, 322, 324, 326, 328, 330, 331, 337, 340, 342, 344, and 353.) Defendant DRL was dismissed on stipulation on October 16, 2015. (Dkt. 355.)[2] Thus, the current parties in this case are plaintiffs and Teva.

Teva asserts that the asserted claims of each of the four patents-in-suit are invalid as obvious under 35 U.S.C. § 103. Teva also raises a written description claim against those patents under 35 U.S.C. § 112. Teva further asserts invalidity of those patents under the on-sale bar provision of 35 U.S.C. § 102. The on-sale bar issue presents not only underlying factual questions, but also a statutory interpretation question addressing the amended text of § 102(a)(1) under the America Invents Act ("AIA"), Pub.L. No. 112-29 (2011). Plaintiffs oppose each of Teva's points on those issues, asserting that the patents are valid and enforceable.

There is also an infringement issue. Teva filed one consolidated ANDA, seeking approval for products at two dif-

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No. 13-5815. Copies of the four patents-in-suit are attached as exhibits to the pleadings, and are trial exhibits. We will simply cite to the patents by page or column and line number.

[2] DRL and plaintiffs have a related action, actively pending in this Court, pertaining to the '724 patent and DRL's pending 505(b)(2) New Drug Application under 21 U.S.C. § 355(b)(2). See Helsinn Healthcare S.A., et al. v. Dr. Reddy's Laboratories, Ltd., et al., Civil Action No. 12-2867. In that case, the Court issued a Memorandum Opinion and Order on April 2, 2015, construing the '724 claim term "a chelating agent." (Civ. Action No. 12-2867, dkt. 91 (Order) and 92 (SEALED Mem. Op.).)

ferent dose levels (0.25 mg and 0.075 mg), and two different treatment indications (chemotherapy-induced nausea and vomiting ("CINV") for the 0.25 mg dose, and post-operative nausea and vomiting ("PONV") for the 0.075 mg dose). The concentration of both proposed Teva products is 0.05 mg/mL, because the 0.25 mg dose solution is 5 mL and the 0.075 mg dose solution is 1.5 mL. The asserted '219 patent claims only specify a 0.25 mg dose, in a 5 mL volume (i.e., concentration 0.05 mg/mL), for CINV. Plaintiffs assert that if the '219 claims are held to be valid, those claims are infringed by Teva's ANDA filing itself, according to the Hatch–Waxman Act, and therefore both generic products applied for in Teva's ANDA must infringe and be enjoined. Teva disputes plaintiffs' legal position and seeks a declaration that its 0.075 mg dose PONV product will not infringe the asserted '219 patent claims.

This Memorandum Opinion constitutes the Court's findings of fact and conclusions of law, pursuant to Federal Rule of Civil Procedure 52(a). For the reasons set forth herein, the Court finds: (1) the person of ordinary skill in the art ("POSA") would be defined as plaintiffs proposed, including skills of a clinician, marketing person, formulator, and pharmaceutical development scientist; (2) the framing of the obviousness issue would be whether it would have been obvious to a POSA in January, 2003 to develop an improved intravenous antiemetic formulation containing palonosetron and (in particular) EDTA; (3) based on the prior art, the selection of palonosetron for development would not have been obvious; (4) based on the prior art, the selection of dosage 0.25 mg for CINV would not have been obvious; (5) based on the prior art, the selection of 0.05 mg/mL concentration would be dose-dependent and would not be obvious; (6) the asserted

claims would not have been arrived at by "routine experimentation"; (7) evidence including commercial success attributable to the claimed formulation, industry skepticism, and long-felt need supports the finding of non-obviousness; (8) the asserted claims are not invalid for lack of written description; (9) the asserted claims were not ready for patenting as of January, 2002; (10) all three pre-January 2002 Helsinn contracts (including the MGI contract, which we find was a contract) meet the "sale or offer for sale" criteria under the pre-AIA on-sale bar test; but (11) none of the three pre-January 2002 Helsinn contracts meet the post-AIA on-sale bar test, as the Court interprets and applies the amended statutory language of 35 U.S.C. § 102(a)(1), because the Oread and SP contracts were entirely confidential, and although the existence of the MGI contract was announced publicly, the claimed invention itself was not disclosed; (12) the asserted claims of the '724, '725, and '424 patents would be infringed by sale of Teva's proposed 0.25 mg/5mL CINV product and 0.075 mg/1.5mL PONV product, as the parties have stipulated; (13) the asserted claims of the '219 patent would be infringed by sale of Teva's proposed 0.25 mg/5mL CINV product, as the parties have stipulated; and (14) the asserted claims of the '219 patent would not be infringed by sale of Teva's proposed 0.075 mg/1.5mL PONV product.

Based on these factual findings, the Court concludes (under the applicable standards of proof on each issue) as follows: (1) Teva did not prove that the '724, '725, '424, or '219 patents are invalid as obvious under § 103, or for lack of written description under § 112; (2) as to Teva's on-sale bar claim of invalidity of the '724, '725, and '424 patents under the pre-AIA § 102(b), Teva proved the "sale or offer to sell" prong as to the Oread, SP, and MGI contracts, but Teva did not prove that the claimed invention was "ready

for patenting" as of January 30, 2002; therefore, Teva did not prove that the '724, '725, and '424 patents are invalid under the on-sale bar; (3) Teva did not prove that the '219 patent is invalid under the post-AIA § 102(a)(1) on-sale bar; (4) assuming that the '724, '725, and '424 patents are valid as the Court has found, the Court agrees with the parties' stipulation that both the 0.075 mg dose and the 0.25 mg dose generic product specified in Teva's ANDA will infringe those three patents; (5) assuming that the '219 patent is valid as the Court has found, the Court agrees with the parties' stipulation that the 0.25 mg dose generic product specified in Teva's ANDA will infringe the '219 patent; and (6) assuming that the '219 patent is valid as the Court has found, the Court further finds that plaintiffs did not prove that the 0.075 mg dose generic product specified in Teva's ANDA will infringe the '219 patent.

Based upon these findings and conclusions, the Court will enter judgment declaring that:

(1) the asserted claims of the '724, '725, and '424 patents are valid and are infringed by both Teva's proposed 0.25 mg and 0.075 mg generic products;

(2) the asserted claims of the '219 patent are valid and are infringed by Teva's proposed 0.25 mg generic product; and

(3) the asserted claims of the '219 patent are valid and are not infringed by Teva's proposed 0.075 mg generic product.

This Memorandum Opinion will be filed under temporary seal, and will be unsealed on or after December 1,

2015, unless a motion to seal is filed by any party. The Court will enter an appropriate judgment.

s/Mary L. Cooper
The Honorable Mary L. Cooper
United States District Judge

Dated: November 13, 2015

No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC., AND
TEVA PHARMACEUTICAL INDUSTRIES, RESPONDENTS

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION TO CERTIORARI

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QUESTION PRESENTED

Whether this Court should review the Federal Circuit's factual conclusion that Helsinn's sale agreement with a third party publicly disclosed its claimed invention "in detail" (Pet. 33a) more than a year before it filed its patent application, thus triggering the "on sale" bar on patentability set forth in 35 U.S.C. §102(a).

CORPORATE DISCLOSURE STATEMENT

The parent companies of Respondent Teva Pharmaceuticals USA, Inc. are: Orvet UK Unlimited, Teva Pharmaceutical Holdings Cooperative U.A., Ivax LLC (f/k/a IVAX Corporation), Teva Pharmaceuticals Europe, B.V., and Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Pharmaceuticals USA, Inc.

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A. The AIA's plain text confirms that Congress did not change the settled meaning of "on sale," which Helsinn conceded was a term of art. 19

B. Helsinn has no answer for §102(b), which expressly distinguishes between public and private disclosures. 25

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INTRODUCTION

This case involves the first Federal Circuit decision addressing the scope of the AIA's on-sale bar. Helsinn insists that the decision warrants immediate review because it "swept broadly" and was "'untethered to the statutory text.'" Pet. 33, 3. Yet Helsinn has presented a caricature of the decision, which not only is a unanimous, fact-bound ruling limited to "the circumstances involved" and "this particular [sales] [a]greement," but is grounded in the Patent Act's text, structure, and 200-year history. Pet. 20a, 43a.

Helsinn did not contest that history below. It conceded that "on sale" was a "term[] of art"—an "established term[]" that historically covered secret sales—and that even today the on-sale bar may be triggered without "disclosure of 'the details of the * * * invention.'" Beyond the vehicle problems created by these concessions, Helsinn asks this Court to second-guess the lower court's *factual* conclusion that the sale here was "public" rather than "secret." It thus turns out that the "question presented" is not really presented. Not surprisingly, no Federal Circuit judge supported en banc review—or even requested a vote.

Helsinn offers no convincing reason for this Court to grant review either. *First*, as to the ruling's scope, Helsinn criticizes the court below for stating that "if the existence of the sale is public, the details of the invention need not be publicly disclosed" to trigger the bar. Pet. 33. But the court did not just find that the *existence* of Helsinn's sale was public; it found that Helsinn disclosed the claimed drug formulation "in detail." Pet. 33a. The court declined to rule "more broadly than necessary," deferring any decision on "cases involv[ing] a public use where the invention

was not * * * disclosed" or "'secret sale' cases." Pet. 37a, 38a, 39a. Helsinn ignores this.

Helsinn also ignores that the government did not support en banc review, having stated at argument: "[I]f this Court concludes that this was in fact a sale that made the invention available to the public, that will not cause us any heartburn." That is what the court concluded. As Judge O'Malley explained, "the standard governing secret sales * * * simply is not implicated" here, and Helsinn's contrary view rests on the "mischaracterization[]" of "a single sentence." Pet. 4a, 6a n.1.

According to Helsinn, Judge O'Malley's opinion is "revisionist." Pet. 33. But in denying Helsinn's stay motion, the other two panel members fully endorsed her opinion, reiterating that the decision is "narrow." App., *infra*, 2a. Remarkably, Helsinn does not mention this order—or even provide it to the Court. But it confirms that this case is a poor vehicle to address the question presented, and that Helsinn and its pro-patentee amici seek review not to narrow a broad decision, but to broaden a narrow one.

Second, even if the sale here were secret, the decision was correct for additional reasons given by the panel and Judge O'Malley. Indeed, that Helsinn publicized its claimed formulation "in detail" (Pet. 33a) makes this an especially easy case. Helsinn's petition glosses over the statute's text, structure, and history —and its own concessions. "On sale" is a term of art with centuries of pre-AIA history; both its ordinary and specialized meanings include *all* sales, public and private. And "when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached." *Air Wis. Airlines Corp.* v.

Hoeper, 134 S. Ct. 852, 861–862 (2014). In fact, even before the on-sale bar existed, this Court held that the Patent Act and the Constitution barred commercially exploiting inventions before patenting them. *Pennock* v. *Dialogue*, 27 U.S. 1 (1829).

The AIA retained the term "on sale" unmodified, without limiting it to public sales, while embedding it in a list of bars that, by contrast, *do* repeatedly include the word "public." Those are powerful textual confirmations that Congress did not "work a foundational change in the theory of the statutory on-sale bar." Pet. 39a. "Congress generally acts intentionally when it uses particular language in one [part] of a statute but omits it in another." *Dep't of Homeland Sec.* v. *MacLean*, 135 S. Ct. 913, 919 (2015) (citations omitted). And as the court below observed, if Congress intended "a sweeping change" to the law, "it would do so by clear language" (Pet. 39a, 43a)—such as "*publicly* on sale."

Helsinn nonetheless insists that Congress worked just such a change—without amending "on sale"—by creating a new bar for claimed inventions "otherwise available to the public." According to Helsinn, "available to the public" is a "series modifier" that works backwards through the list of statutory bars, upending settled precedent as it goes. Pet. 15–16. But such a construction is proper only when the final clause "is applicable as much to the first and other words as to the last." *Paroline* v. *United States*, 134 S. Ct. 1710, 1721 (2014). As Judge O'Malley explained, §102(a)'s catchall clause is *not* as applicable "to the first and other words as to the last," since that reading would create massive "redundancies." Pet. 9a n.2. All the listed words except "on sale" are *already* inherently public or pre-labeled as public. Pet. 8a–9a & n.2.

Thus, the more natural reading is that, in adding "otherwise available to the public" to the statute, Congress confirmed that all public disclosures trigger the bar—even when made orally, or via new technologies. Congress did not shrink the distinct category of *sales* that invalidate patents.

Further, the AIA's next subsection distinguishes between "disclosures" and "public disclosures," which makes no sense if all §102(a) disclosures are public. Helsinn says the disclosures in §102(b) are "different" and "antecedent" (Pet. 19), but never says how. And as we will show, Helsinn's policy arguments fail on their own terms.

This Court is "a court of review, not of first view" (*Cutter* v. *Wilkinson*, 544 U.S. 709, 718, n.7 (2005)), and Helsinn presents a "secret sale" question that was not reached below. And since Helsinn's sale was invalidating under either view of that question, the answer does not matter. "[T]his Court reviews judgments, not opinions" (*Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984)), and both the panel's and Judge O'Malley's opinions support the judgment. Certiorari is not warranted to say which opinion is most powerful.

STATEMENT

A. The history of the on-sale bar

Helsinn briefly mentions the pre-AIA on-sale bar, but neglects its history. To understand the bar's current scope, however, it is vital to understand that beginning nearly 200 years ago—before the on-sale bar existed—this Court has repeatedly held that both the Patent Act and the Constitution bar commercially exploiting inventions before patenting them.

1. The 1790 and 1793 Patent Acts and this Court's decision in *Pennock*

Congress's first patent statute—the Patent Act of 1790—limited patents to matter "not before known or used." Ch. 7, §1, 1 Stat. 110. Similarly, the Patent Act of 1793 barred patenting matter "known or used before the [patent] application." Ch. 11, §1, 1 Stat. 319. Thus, the question arose early whether patents could cover inventions that had already been sold.

This Court addressed that question in *Pennock* v. *Dialogue*, 27 U.S. 1 (1829) (Story, J.). The patent there claimed a process of making hose with pressure-resistant joints. *Id.* at 3, 14. The joints did not reveal the process. But years before seeking a patent, the inventor authorized sales of the hose. *Id.* at 9. Thus, the defendant argued that the invention was "known or used before the application." *Id.* at 11–12.

The Court agreed. Inventions are "known or used" if "known or used by the public," and public use includes "sell[ing] [the] invention publicly." *Id.* at 19.

The Court stressed that allowing inventors to exploit inventions commercially before patenting them would violate not only the Patent Act, but the Constitution. The Patent & Copyright Clause authorizes Congress "'to promote the progress of science and useful arts, by securing *for limited times*, to authors and inventors, the exclusive right to their respective writings and discoveries,'" and "contemplates, therefore, that this exclusive right shall exist but for a limited period." *Id.* at 16–17 (quoting U.S. Const. Art. I, § 8, cl. 8). If inventors could profit from secret inventions, only to patent them later, it would "retard the progress of science":

> If an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention; if he should for a long period of years retain the monopoly, and make, and sell his invention publicly, and thus gather the whole profits of it * * * and then, and then only, when the danger of competition should force him to secure the exclusive right, he should be allowed to take out a patent * * * it would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries.

Id. at 19. Even before the on-sale bar, therefore, the law barred patenting inventions that had been publicly sold. *Id.* at 23; accord *Shaw* v. *Cooper*, 32 U.S. 292, 322–323 (1833); *Pfaff* v. *Wells Elec., Inc.*, 525 U.S. 55, 64 (1998). And as the Court later reaffirmed, "the inventor who designedly, and with the view of applying [his invention] indefinitely and exclusively for his own profit, withholds his invention from the public, comes not within the policy or objects of the Constitution or acts of Congress." *Kendall* v. *Winsor*, 62 U.S. 322, 328 (1858).

2. Congress adopts the on-sale and public use bars in 1836

The Patent Act of 1836 continued to bar patenting inventions "known or used by others." Ch. 357, §6, 5 Stat. 117. But Congress also added language barring patents on inventions that were "in public use or on sale." *Ibid.* These distinct restrictions are now known as the "public use" and "on sale" bars.

Early on, this Court read "public use" to bar patenting where "an inventor, having made his device, gives or sells it to another, to be used * * * without

limitation or restriction, or injunction of secrecy." *Egbert* v. *Lippmann*, 104 U.S. 333, 336 (1881). "[S]uch use is public, even though the use and knowledge of the use may be confined to one person" and the invention "cannot be seen or observed by the public eye." *Ibid.* (invalidating a patent on a corset stay previously worn under a woman's dress).

Unlike items in "public use," however, items "on sale" have never had to be sold publicly to defeat patentability. As then-Judge Stevens once explained, "the 'public use' and the 'on sale' objections" are "distinct"; "[t]here may be a public use prior to any sale," and, "alternatively, there may be sales which neither the vendor nor the purchaser desires to make public but which nevertheless" trigger the bar. *Dart Indus., Inc.* v. *E. I. Du Pont De Nemours & Co.*, 489 F.2d 1359, 1364 n.8 (7th Cir. 1973). Following this approach, courts have consistently invalidated patents on commercially exploited inventions.

The leading lower-court case is *Metallizing Engineering Co.* v. *Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), which this Court endorsed in *Pfaff*. 525 U.S. at 68. As Judge Learned Hand explained, an inventor "shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." *Ibid.* (quoting *Metallizing*, 153 F.2d at 520). This rule "had its origin" in *Pennock*'s holding that "it would materially retard the progress of science" if inventors could profit from their inventions while "hold[ing] back from the knowledge of the public the secrets [thereof]." 153 F.2d at 520, 518 (quoting *Pennock*, 27 U.S. at 19). And the rule applies "regardless of how little the public may have learned about the invention." *Id.* at 520.

Following *Pennock* and *Metallizing*, myriad courts have held that the on-sale bar reaches confidential sales.[1] As these courts recognize, "[t]he primary policy underlying the 'public use' case is that of detrimental public reliance, whereas the primary policy underlying an 'on-sale' case is that of prohibiting the commercial exploitation of the design beyond the statutorily prescribed time period." *Cont'l Plastic Containers* v. *Owens Brockway Plastic Prods., Inc.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998). Thus, "[a]ny attempt to use [an invention] for a profit * * * for a longer period than [one year] before the application, would deprive the inventor of his right to a patent." *Pfaff*, 525 U.S. at 65 (citation and emphasis omitted).

Helsinn thus conceded below that "on sale" was a "term[] of art" under pre-AIA law—an "established term[]" that has always appeared in a list of "public" activities, yet captured secret sales. C.A. Br. 41.

3. In the AIA, Congress considers removing the on-sale bar, but declines to do so

In 2011, Congress passed the AIA. Previously, the Act provided that "[a] person shall be entitled to a patent unless":

> the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application[.]

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[1] Pet. App 35a n.7, 40a (collecting cases); *Medicines Co.* v. *Hospira, Inc.*, 827 F.3d 1363, 1376–1377 (Fed. Cir. 2016) (en banc) (same); *Mfg. Research Corp.* v. *Graybar Elec. Co.*, 679 F.2d 1355, 1362 (11th Cir. 1982); *Hobbs* v. *U.S. Atomic Energy Comm'n*, 451 F.2d 849, 860 (5th Cir. 1971).

35 U.S.C. §102(b) (2010).

For several years, Congress considered removing the on-sale bar, thus eliminating "secret activities as grounds for invalidity." 154 Cong. Rec. 22,631 (2008) (Sen. Kyl). For example, in 2005, Congress considered stating:

> (1) the claimed invention was patented, described in a printed publication, or otherwise publicly known[.]

H.R. 2795, 109th Cong.; see also, *e.g.*, S. 3818, 109th Cong.; S. 3600, 110th Cong. These versions failed.

The AIA, however, restored the term of art "on sale" to the statutory list. Today, "[a] person shall be entitled to a patent unless":

> the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention[.]

35 U.S.C. §102(a) (2011).

B. The invention, the publicized agreement for its sale, and the district court's ruling

Helsinn's '219 patent, issued in 2013, claims a low-dosage form of palonosetron, a drug long used to treat chemotherapy-induced nausea and vomiting. In 2001, over a year before the relevant patent application, Helsinn contracted with MGI Pharma "to distribute, promote, market, and sell" Helsinn's later-patented "0.25 mg and 0.75 mg palonosetron products," or "whichever" dosage FDA approved. Pet. 29a, 23a.

MGI disclosed the sale, and a partially redacted copy of the Agreement, to the SEC. Pet. 5a. Together, the parties publicly announced the Agreement, which "described the claimed drug formulation 'in detail.'" *Ibid.* (quoting Pet. 33a). Only the drug's "price" and "specific dosage[s]" were not publicly disclosed. Pet. 24a.

When Helsinn sued Teva, Teva answered that the MGI Agreement triggered the on-sale bar. The district court agreed that the Agreement "was a contract for a future commercial product." Pet. 164a. Nevertheless, it deemed the on-sale bar inapplicable, reasoning that the invention was not "ready for patenting" or "available to the public." Pet. 210a, 180a.

C. The Federal Circuit finds the invention "on sale" under the particular agreement and circumstances involved here

Teva appealed, invoking the AIA's text, structure, and history. Helsinn rejoined that the legislative history was "authoritative," complaining that "Teva denounce[d] [it]." C.A. Br. 50, 53 (citations omitted). Helsinn cited "the additional statutory language" ("otherwise available to the public"), numerous floor statements, and various committee reports. Pet. 37a; C.A. Br. 50–58.

The panel reversed, finding the invention "overwhelming[ly]" ready for patenting. Pet. 47a. Further, the panel held that, under the UCC, the Agreement "constituted a sale of the claimed invention—the 0.25 mg dose—before the critical date." Pet. 43a. The Agreement "described the palonosetron formulation in detail and Helsinn does not assert that the 0.25 mg dose described in the [MGI] Agreement does

not embody the asserted claims." Pet. 33a. Helsinn does not contest these rulings.

The court also held that the sale triggered the on-sale bar. In so holding, it emphasized that it "d[id] not find that distribution agreements will always be invalidating," just "that this particular Supply and Purchase Agreement is." Pet 43a. Helsinn had both publicly announced its sale and described the claimed formulation "in detail." Pet. 33a. The court concluded that the AIA "did not change the statutory meaning of 'on sale' in the circumstances involved here" (Pet. 20a), adding that, even if Helsinn had not disclosed the invention in detail, Congress would use "clear language" if it intended "a sweeping change to our on-sale bar jurisprudence" (Pet. 43a).

As to Helsinn's "floor statements," the court noted that they are "typically not reliable." Pet. 36a. Regardless, the statements nowhere suggested that Congress overruled the numerous decisions "explicitly reject[ing] a requirement that the details of the invention be disclosed." Pet. 40a. Helsinn's sale thus triggered the on-sale bar.

D. The Federal Circuit unanimously denies rehearing

Helsinn sought rehearing, but no judge requested a vote and review was denied. Judge O'Malley concurred, emphasizing the narrowness of the decision, providing additional "principles of statutory interpretation" that support it (Pet. 9a–12a), and correcting Helsinn's "mischaracterizations" thereof (Pet. 4a–7a).

As Judge O'Malley observed, Helsinn mischaracterized the decision by suggesting that: (1) the on-sale bar will be triggered "every time the fact of a sale is disclosed to the public"; (2) "all supply-side agree-

ments with third-party distributors will constitute invalidating transactions"; and (3) "our holding is inconsistent with our en banc decision in *Medicines Co.* v. *Hospira*, 827 F.3d 1363 (Fed. Cir. 2016)." Pet. 4a. As she explained, the decision "does not suggest that publicly announced agreements will always trigger the on-sale bar," or "that secret sales never will." Pet. 4a–5a. Rather, "the confidential nature of a transaction is just one of several factors" in a "fact-intensive" analysis, and "[a]ll that our panel opinion held was that the particular agreement at issue triggered the on-sale bar, in part—but not exclusively—because it was made public." Pet. 5a, 6a.

Judge O'Malley also noted that Helsinn made "few legal arguments" to support its interpretation. Pet. 8a. "Helsinn's only argument directed to the text" was "that the new phrase 'or otherwise available to the public'" modifies "'on sale,'" but that reading had "several problems." *Ibid.* For example, such "series modifiers" work only when the modifier "appli[es] as much to the first and other words as to the last"; but "otherwise available to the public" is "not equally applicable to all preceding phrases because each phrase * * * recites a disclosure that is necessarily public. Helsinn's reading * * * would therefore create redundancies." Pet. 9a & n.2.

Numerous other factors confirmed "that Congress meant to leave the on-sale bar intact." Pet. 9a. For instance, "Congress chose not to modify the term 'on sale,'" confirming that it "intended for that term to take on the meaning that courts had attributed to it for well over a century." *Id.* at 9a–10a. Further, §102(b)(1) refers to both "disclosures" and "public disclosures"; but "[i]f all prior art events—i.e., all 'disclosures'—recited in §102(a) were already public disclo-

sures, the word "publicly * * * would be redundant." Pet. 10a–11a. In short, "[a]s the panel opinion noted, '[i]f Congress intended to work such a sweeping change to our on-sale bar jurisprudence * * * it would [have done] so by clear language,'" not in a manner "at odds with so many principles of statutory interpretation." *Ibid.*

Helsinn moved to stay the mandate. In its order denying the stay, which Helsinn omits from its appendix, the panel endorsed "the reasons set forth" in "Judge O'Malley's concurrence" and reiterated that "the decision is a narrow one." App., *infra*, 2a. The Chief Justice likewise denied a stay. 17A785. Teva has since launched generic palonosetron.

REASONS FOR DENYING THE PETITION

I. Certiorari should be denied because the decision below is narrow, fact-bound, and rife with vehicle problems.

According to Helsinn, this case "involves a secret sale" and the decision below "swept broadly." Pet. 22, 33 (quoting Pet. 43a). Both contentions require ignoring much of what the Federal Circuit actually said, and Helsinn's own concessions. The decision below is expressly narrow, fact-bound, and confined to the unusual circumstances here; and it is the first to interpret the AIA's on-sale bar. Further, the petition rests on a *factual* challenge to the court's conclusion that Helsinn's sale was public—a major vehicle problem. Even if the court had incorrectly resolved that issue, its decision would not warrant certiorari. Not surprisingly, no judge below supported rehearing.

A. The Federal Circuit limited its decision to the unusual agreement here and declined to reach the secret-sale issue.

Judge O'Malley explained that "[a]ll that our panel opinion held was that the *particular* agreement at issue triggered the on-sale bar." Pet. 5a. By Helsinn's lights, that represents only Judge O'Malley's view. Pet. 13, 33. Helsinn is mistaken.

First, in language that Helsinn never mentions, the court limited its ruling to "the circumstances involved here" and "this particular * * * Agreement." Pet. 20a, 43a. "We do not find that distribution agreements will always be invalidating under § 102," the court held. Pet. 43a. "We simply find that this particular Supply and Purchase Agreement is." *Ibid.* The court declined "to decide this case more broadly than necessary," purposely not reaching "cases involv[ing] a public use where the invention was not * * * disclosed to the public" or "'secret sale[s].'" Pet. 37a, 38a, 39a. Helsinn ignores these passages. But even its own amicus below admitted that the court "cabin[ed] the decision to the facts." Dkt. 166 at 4.

Second, the court's reasoning follows from Helsinn's unique distribution agreement, its extensive disclosures, and its exploitation of its product. Explaining that patentees "must unambiguously place the invention on sale, as defined by the patent's claims," the court observed: "that is clearly the case here." Pet. 33a. Helsinn did not merely publicize the sale's *existence*; the sale documents "described the claimed drug formulation 'in detail.'" Pet. 5a (quoting Pet. 33a). As Judge O'Malley elaborated:

> Helsinn did not just disclose the fact that it had entered into a supply agreement with MGI; a par-

> tially-redacted copy of the Agreement itself was included with MGI's Form 8-K filing. As the panel noted, the Agreement described the claimed drug formulation "in detail." The Agreement also "expressly contemplated" the passage of title, and made clear that Helsinn "commercially marketed its invention before the critical date."

Ibid. (citations omitted).

In other words, that a sale is "publicly announced" is "not dispositive." Pet. 5a. Rather, courts must also consider "the nature of the disclosure"—a "fact-intensive" inquiry. Pet. 4a, 6a. Thus, to "suggest that publicly announced agreements will always trigger the on-sale bar" is a "mischaracterization[]" based "on a single sentence.'" *Id.* at 4a. Helsinn and its amici repeat the mischaracterization here.

Third, Helsinn never mentions that the full panel endorsed Judge O'Malley's concurrence. In denying Helsinn's motion for a stay pending certiorari, the panel explained: "For the reasons set forth in the majority opinion, and in Judge O'Malley's concurrence to the denial of rehearing, the decision is a narrow one." App., *infra*, 2a. Yet Helsinn accuses Judge O'Malley of "revisionis[m]" without acknowledging the stay order—or even including it in its appendix. Pet. 33. And since that order speaks directly to whether the ruling below is "narrow," Helsinn's omission contravenes Rule 14.1(i)'s mandate that the appendix "shall contain" all "relevant opinions [and] orders."

Finally, no judge even requested a poll on rehearing en banc. Helsinn says the on-sale bar "'is probably the greatest source of litigation involving * * * challenges to patent validity.'" Pet. 28 (citing Mueller, *Patent Law* 263 (5th ed. 2016)). But the full

quotation says "*35 U.S.C. §102(b) (2006)* challenges"—meaning pre-AIA challenges including often-litigated issues such as anticipation. And even as to the on-sale bar, the author explains that "many" of the pre-AIA cases addressed "what state of development the invention must be in"—which has nothing to do with whether the invention is on sale. Mueller, *supra*, at 265.

Further, in the years since the AIA passed in 2011, this case "provid[ed] the * * * first potential opportunity to determine whether the AIA changed the law of on sale bar." *Id.* at 333 n.375. It is thus fanciful to call review "urgent." Pet. 29. Future Federal Circuit panels remain free to resolve the question Helsinn (incorrectly) says is presented here. Rather than credit the prognostications of Helsinn and its amici, this Court should let that question percolate.

B. This case is a poor vehicle to decide the scope of the AIA's on-sale bar.

The opinions below confirm that this case is a poor vehicle to address the question presented. Yet Helsinn ignores both the court's narrowing language and Helsinn's concession that inventions may be on sale without "disclosure of 'the details.'" Pet. for Reh'g En Banc 10.

1. The court concluded that Helsinn's sale was public, and the petition contests that factual determination.

a. Having found that this case involves a public sale, the court below "decline[d] to address" "cases [that] involved a public use where the invention was not * * * disclosed to the public," or "'secret sale' cases." Pet. 38a, 39a. These passages place in proper context the court's statement that "if the existence of

the sale is public, the details of the invention need not be publicly disclosed" to trigger the bar. Pet. 33. As Judge O'Malley explained, the decision below did not turn on this "single sentence," and "the standard governing secret sales * * * simply is not implicated" here. Pet. 4a, 6a n.1. In short, the court found that the sale was public, and there will be time enough for this Court to address secret sales where actually presented in a future case.

Helsinn's petition thus challenges the court's *factual* conclusion that the sale here was "public," not "secret." Pet. 22 (this case "involves a secret sale"). Attempting to avoid this difficulty, Helsinn suggests that Teva "conceded that 'the allegedly invalidating sale at issue did not make the invention publicly available.'" Pet. 11, 22 (citation omitted). But Teva conceded no such thing, and Helsinn's assertion is supported only by a citation of *the government's* brief. Teva has consistently contended not only that the bar may be triggered by *either* public or secret sales, but that "even if the on-sale bar under the AIA does include a 'public' requirement—which it does not—the Supply and Purchase Agreement still constitutes an invalidating offer for sale." *E.g.*, Dkt. 312 at 3 (D.N.J.); see *ibid.* ("the plain fact is that the commercial contract between Helsinn and MGI was 'public'"); Pet. 151a ("Teva additionally argues that Helsinn violated the on-sale bar even under Helsinn's proposed interpretation of the AIA, as the supply agreement was publicized and MGI is a member of the public."); C.A. Reply Br. 12. And even if the court below had erred in resolving that issue, review is not warranted to correct "erroneous factual findings." Rule 10.

b. Nor does the ruling here portend "uncertainty" at the PTO. Pet. 28. Helsinn never mentions it, but

the government, after participating at the panel stage, did not support en banc review. That is not surprising. The PTO's guidance, which lacks the force of law, states only that a "secret sale or use activity does not qualify as prior art" (78 Fed. Reg. 11062 (Feb. 14, 2013)); and the court below found that the sale "described the claimed drug formulation 'in detail.'" Pet. 5a (quoting Pet. 33a).

As the government's counsel stated at argument below, "if this Court concludes that this was in fact a sale that made the invention available to the public, that will not cause us any heartburn."[2] That is what the court concluded. But even if it had reached the secret-sale question, it would not have been disruptive to hold that "on sale," a term of art, still covers nonpublic sales.

2. Below, Helsinn forfeited key points that it asks this Court to take up.

Helsinn's positions below further confirm that this case is anything but an "ideal vehicle" to resolve the question presented. Pet. 32. For example, Helsinn complains that the court below "completely ignored" the statutory definition of "claimed invention" (Pet. 22), while ignoring that Helsinn *never cited it*.

But it is worse than that. Helsinn affirmatively disclaimed the position "that an invalidating offer requires disclosure of 'the details of the * * * invention.'" Pet. for Reh'g En Banc 10. According to Helsinn, to trigger the on-sale bar, disclosing "the *existence*" of the sale was not enough, disclosing "the *details*" of the invention was more than enough, and disclosing the claimed invention without the details

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[2] https://bit.ly/2I8s3bo (minute 32:52–33:10).

was just right. Helsinn now abandons its "Goldilocks" theory—demanding that every detail of "the claimed invention" be disclosed (Pet. 22) and assailing the statement that "if the existence of the sale is public, the details of the invention need not be publicly disclosed" (*id.* at 43a). Pet. 4, 12–13, 21, 32–33. Helsinn should be held to its position below.

Regardless, Helsinn neglects portions of the opinions below explaining how the sale documents here "described the claimed drug formulation 'in detail'" (*id.* at 5a (quoting Pet. 33a)) and "constituted a sale of the claimed invention" (Pet. 43a). Such passages confirm that Helsinn faults the Federal Circuit's *application* of its legal framework to these facts, not the framework itself. Review should be denied.

II. Certiorari should also be denied because, whether public or secret, the invention here was on sale.

Certiorari should also be denied because, whether the sale here was "public" or "secret," the decision below is firmly grounded in the AIA's text, structure, history, and purpose. See *Chevron*, 467 U.S. at 842 ("this Court reviews judgments, not opinions").

A. The AIA's plain text confirms that Congress did not change the settled meaning of "on sale," which Helsinn conceded was a term of art.

1. Under the on-sale bar's plain terms, offering to sell an invention will start the one-year clock to apply for a patent regardless of whether the offer discloses all "details." Pet. 40a–43a. A "sale" is a "transfer of property for money or credit" (*Random House Webster's Unabridged Dictionary* 1693 (2d ed. 2001)), a definition that covers private transfers; and myriad

courts so held before the AIA. And as the court below recognized: "If Congress intended * * * a sweeping change to our on-sale bar jurisprudence," "it would do so by clear language." Pet. 43a.

After all, Congress "does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman* v. *Am. Trucking Ass'n*, 531 U.S. 457, 468 (2001). Yet if Helsinn is correct, Congress "hid[] an awfully big elephant in a tiny mousehole," as it reads "a 'residual clause' and a few passages of legislative history to overturn nearly two centuries of consistent U.S. patent policy." Merges & Duffy, *Patent Law and Policy* 360 (7th ed. 2017). As Helsinn's own authority admits, "the AIA did not sub silentio overrule th[is] well-established case law." Mueller, *supra*, at 331.

By adding "otherwise available to the public" to §102, Congress simply confirmed that patents will always be barred by public disclosures—even if made orally, or via new technologies, rather than, as before, in a "printed publication." The lower courts were divided on that question, so Congress had reason to address these "known unknowns." See, *e.g.*, *In re Klopfenstein*, 380 F.3d 1345, 1349 n.4 (Fed Cir. 2004) (oral presentations); *Diomed, Inc.* v. *Angiodynamics, Inc.*, 450 F. Supp. 2d 130, 141 (D. Mass. 2006) (video).

Although Helsinn never mentions it, Helsinn conceded below that "on sale" was a "term[] of art"—an "established term[]" that has always been listed together with "public" activities, yet also captured non-public sales. C.A. Br. 41. The court agreed, citing numerous authorities. Pet. 35a n.7, 39a–43a. And if

"on sale" covers confidential sales, the claimed invention need not be made public.

This reading is hardly "untethered to the statutory text" (Pet. 3); it reflects the natural, historic meaning of "on sale." After all, "when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached." *Hoeper*, 134 S. Ct. at 861–862. Had Congress wished to overrule settled law, it could have said "publicly on sale." Including some form of the word "public" is how Congress limited the surrounding bars, and "Congress generally acts intentionally when it uses particular language in one [part] of a statute but omits it in another"—particularly where, as here, the disparate terms appear "in the same sentence." *MacLean*, 135 S. Ct. at 919. Further, public sales are already covered by the public use bar. *E.g.*, *Egbert*, 104 U.S. at 336 (selling "to another * * * without limitation" is public use).

2. Helsinn's sole textual response—that "otherwise available to the public" is a "series modifier" restricting the whole list to public activities (Pet. 15–16)—creates glaring redundancies. A clause is a series modifier only if it "is applicable as much to the first and other words as to the last." *Paroline*, 134 S. Ct. at 1721. But as Judge O'Malley explained, §102(a)'s catchall clause is *not* equally applicable "to the first and other words as to the last," because all the words except two—"on sale"—are inherently public or pre-labeled as public. Pet. 8a–9a & n.2.

The AIA bars a patent if the invention "was *patented*, described in a printed *publication*, or in *public* use, on sale, or otherwise available to the public" (emphases added). "Patented" needed no modification because "[p]atents are public records." *Boyden* v.

Burke, 55 U.S. 575, 582 (1852). So too with "printed *publications*" and items "in *public* use." *Klopfenstein*, 380 F.3d at 1348 ("the key inquiry" is whether references are "'publicly accessible'"). To read "otherwise available to the public" as modifying these terms creates "hopeless[] redundan[cies]." *Lockhart* v. *United States*, 136 S. Ct. 958, 965 (2016)). And a clause is not a series modifier where "it takes more than a little mental energy to process the individual entries in the list, making it a heavy lift to carry the modifier across them all." *Id.* at 963.

According to Helsinn, *United States* v. *Standard Brewery, Inc.*, 251 U.S. 210 (1920), shows otherwise. Pet. 16. The items listed there, however, were not pre-labeled. Rather, the statute referred to "beer, wine, or other intoxicating [beverages]." 251 U.S. at 218. For that statute to be analogous to §102(a), it would have to refer to "intoxicating wine"; and "beer" would have to be a term of art that captured nonalcoholic beer. That is the situation here, where multiple terms are pre-labeled "public" and "on sale" is a term of art covering nonpublic sales.

3. Recognizing these textual difficulties, Helsinn initially omits "patents" and "described in a printed publication" from its quotation of the statute (Pet. 4), but ultimately concedes that such disclosures "are, by their very nature, publicly available." Pet. 15. Not to worry, says Helsinn—the backwards work of "otherwise available" stops abruptly at the "or" in the series, such that the modifier applies only to a subseries in the list—which Helsinn dubs "the final three-item series." Pet. 18 n.4. But that is just the kind of mental gymnastics that show why §102(a)'s catchall clause is not a series modifier. Carrying the modifier

across the list is such a "heavy lift" (*Lockhart*, 136 S. Ct. at 963) that Helsinn must cut down the list.

Even this drastic measure, moreover, cannot save Helsinn's interpretation. Because items in "public use" are already public, applying "otherwise available to the public" to Helsinn's preferred subseries creates a "hopeless[] redundan[cy]" (*id.* at 965)—"in public use available to the public." Helsinn answers that, before the AIA, "public use" was interpreted "to include certain types of secret uses." Pet. 17. Not so. This Court's longstanding test for "public use" is providing "to another * * * without limitation or restriction"—"such use is public." *Egbert*, 104 U.S. at 336. And if "public use" covered secret uses, it would be odd for Congress to change the statute's meaning by repeating that very word ("public") in a later catchall phrase.

No matter how Helsinn slices §102(a), it cannot make "on sale" mean "*publicly* on sale." Congress did not say that. And Helsinn's contrary reading—that Congress changed a term of art with a carom shot, by adding a later catchall phrase—creates incurable "redundancies." Pet. 8a–9a & n.2 (O'Malley, J.).

4. Rather than modifying the preceding series, the catchall phrase in §102(a) falls within the default rule that a "limiting clause" applies "only to the last antecedent." *Barnhart* v. *Thomas*, 540 U.S. 20, 27 (2003). That is, "to the public" limits only "otherwise available." Helsinn says the issue "is not whether 'to the public' modifies 'otherwise available' (it does), but whether the whole phrase "or otherwise available to the public" informs the meaning of the two parallel phrases that precede it (again, it does)." Pet. 17. But *Barnhart* rejected an indistinguishable attempt to

rewrite the first half of a sentence based on a modifier attached to the second half. Like Helsinn's reliance on "otherwise," the argument in *Barnhart* depended on over-reading the word "other."

Barnhart involved a catchall clause in a statute governing disability benefits:

> An individual shall be determined to be under a disability only if * * * he is not only unable to do his previous work but cannot * * * engage in any other kind of substantial gainful work which exists in the national economy[.]

42 U.S.C. §423(d)(2)(A). The agency refused to label an applicant disabled because she could do her previous work, declining to inquire whether that work still "exist[ed] in the national economy." 540 U.S. at 22. That is, the agency would not read "which exists in the national economy" to modify "previous work." *Id.* at 22–23.

This Court sided with the agency, holding that the "limiting clause" ("which exists in the national economy") applied only to the "last antecedent" ("any other kind of substantial gainful work"). 540 U.S. at 26. In so holding, the Court followed precedent that similarly read another catchall clause. *Ibid.* (citing *FTC* v. *Mandel Bros.*, 359 U.S. 385, 389 & n.4 (1959), which held "that the 'limiting clause is to be applied only to the last antecedent,'" which did not include any item in the preceding list). This was not just a matter of deferring to the agency; the Court endorsed the agency's reasoning with an illustration of its own.

Specifically, the Court cited "the case of parents who, before leaving their teenage son alone in the house for the weekend, warn him, 'You will be punished if you throw a party or engage in any other ac-

tivity that damages the house.'" 540 U.S. at 27. The Court continued: "If the son nevertheless throws a party and is caught, he should hardly be able to avoid punishment by arguing that the house was not damaged. The parents proscribed (1) a party, and (2) any other activity that damages the house. As far as appears from what they said, their reasons for prohibiting the home-alone party may have had nothing to do with damage to the house—for instance, the risk that underage drinking or sexual activity would occur." *Ibid.* "And even if their only concern was to prevent damage," the parents "might have wished to preclude all argument," "by specifying and categorically prohibiting the one activity—hosting a party—that was most likely to cause damage." *Id.* at 28.

As in *Barnhart* and *Mandel*, the phrase "to the public" modifies only the last antecedent—"otherwise available." Congress had powerful reasons for withholding patents on items "on sale" privately; otherwise, inventors could extend their monopolies by gaming the system. *Infra* at 30–32. And even if Congress aimed only to encourage inventors to publicize their discoveries, Congress may have wished to preclude all argument by categorically barring patents after all sales, public or private. Certiorari is unwarranted.

B. Helsinn has no answer for §102(b), which expressly distinguishes between public and private disclosures.

Helsinn's reading of §102(a) also runs headlong into the Act's next subsection—which distinguishes between "disclosures" and "public disclosures." Specifically, §102(b)(1) creates "[e]xceptions" to §102(a)—including a grace period whereby "[a] disclosure made

1 year or less before" the filing date "shall not be prior art" if either "(A) the disclosure was made by the inventor"; or "(B) the subject matter disclosed had, before such disclosure, been *publicly disclosed* by the inventor." (Emphasis added.) Thus, an inventor's "['disclosure'] will not bar her from patenting * * * within a year after that disclosure"; and an inventor's "'public disclosure'" immunizes her filing "from all prior art, not just [her own]." Lemley, *Does "Public Use" Mean the Same Thing It Did Last Year?*, 93 Tex. L. Rev. 1119, 1128 (2015).

If, as Helsinn posits, all §102(a) disclosures are "public," then distinguishing between "disclosures" and "public disclosures" is incoherent. But if "'public use' and 'on sale' have the same meaning they have always had"—if "on sale" captures confidential sales —"the distinction between disclosures and public disclosures makes sense." *Ibid.* Why? Because "'disclosures' means all types of 'prior art'"—"includ[ing] some that are not public." *Ibid.*; see 42 Intellectual Property Professors' C.A. Amicus Br. (Dkt. 43) 2–5.

Further, the distinction between "public disclosures" and "disclosures" goes to §102(b)(1)'s "animating principle"—namely, that "to earn a grace period as against a third party who has begun to bring an invention to the attention of the public, an inventor must confer some benefit on the public." Merges, *Priority and Novelty Under the AIA*, 27 Berkeley Tech. L.J. 1023, 1042 (2012). And that benefit must be "a full-on public disclosure." *Ibid.* Helsinn's reading thus guts "the essence of the new third-party grace period." *Ibid.*; see Merges & Duffy, *supra*, at 360–361.

Helsinn and its amici have no comprehensible answer. Helsinn speculates as to why "Congress did *not*

use the word 'publicly'" in parts of §102(b). Pet. 19 (emphasis added); see *ibid.* ("Congress had no need to use the term 'public' to describe those disclosures"). Yet Helsinn never explains why Congress *did* refer to "public disclosure[s]"—except to say that such disclosures are "different" and "antecedent." Pet. 19. How? Helsinn never says. Instead, it declares that "the term 'public[]' in that provision does nothing to undermine the proposition that all Section 102(a)(1) prior art must be 'available to the public.'" Pet. 19-20. That is merely a conclusion.

Helsinn postulates that a mere "disclosure" (unlike a "public disclosure") might refer to patent applications. Pet. 20 n.5. But Congress devoted the very next subsection (§102(b)(2)) to the effect of "Disclosures appearing in applications and patents." That subsection would be superfluous if §102(b)(1) captured such applications.

In short, Helsinn's reading gives no meaning to "public disclosure." That violates the "fundamental canon" that "the words of a statute must be read in their context and with a view to their place in the overall statutory scheme"—as a "coherent," "harmonious whole." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (quotations omitted).

C. Congress repeatedly declined to adopt bills that did what Helsinn wishes.

The AIA's drafting history further supports the decision below, as Congress repeatedly rejected bills that did what Helsinn wishes. Ignoring this, Helsinn calls the decision below "indefensible," "profoundly flawed," and "outmoded" (Pet. 15, 34) for considering floor statements. But it was *Helsinn* that said "[the court] should look to the floor statements." Pet. 36a.

And both the drafting history and floor statements support the decision below.

1. As Judge O'Malley observed, "Congress several times considered, but rejected, the very changes to the on-sale bar Helsinn urges us to conclude were actually made." Pet. 12a. Early bills proposed repealing the on-sale bar, thus "eliminating confidential sales" as "grounds for invalidity." 154 Cong. Rec. 22,631 (2008) (Sen. Kyl). But consider how the legislation evolved:

2005 "(1) the claimed invention was patented, described in a printed publication, *or otherwise publicly known*" (H.R. 2795)

[redacted]

2008 "(1) the claimed invention was patented, described in a printed publication, *or otherwise made available to the public (other than through testing undertaken to reduce the invention to practice)*" (S. 3600)

[redacted]

Thus, from 2005 to 2008, the bills eliminated the on-sale bar. By 2011, however, it was back to stay, prompting Senator Kyl and two others to object that Congress had put "non-public" uses back into the definition of prior art. S. Rep. No. 111–18, at 60 (2009).

After losing in committee, some senators took to the floor, announcing that the new §102 did not mean

what it said. But their statements are "strategic manipulations of legislative history to secure results [members] were unable to achieve through the statutory text." *Exxon Mobil Corp.* v. *Allapattah Services, Inc.*, 545 US 546, 568 (2005); see Merges & Duffy, *supra*, at 361 (calling Senator Kyl's statements "wishful thinking"). Courts may "not assume that Congress intended to enact statutory language that it has earlier discarded." *Chickasaw Nation* v. *United States*, 534 U.S. 84, 93 (2001). Rather, when Congress rejects "the very language that would have achieved the result [that a party] urges," that "weighs heavily against [its] interpretation." *Hamdan* v. *Rumsfeld*, 548 U.S. 557, 579–580 (2006).

2. Rather than grapple with the drafting history, Helsinn presses floor statements (Pet. 21), as it did below, prompting Teva to reply that "the statutory text" is "authoritative" (C.A. Br. 21–22). The Federal Circuit agreed that "floor statements are typically not reliable," but considered them at Helsinn's insistence. Pet. 36a. The court's caution was warranted, as "even a bill's sponsor['s views] are not controlling." *Mims* v. *Arrow Fin. Servs., LLC*, 132 S. Ct. 740, 752 (2012); cf. *Exxon*, 545 U.S. at 568 (same for "committee reports").[3]

Even the floor statements, however, "[a]t most" voiced concern with "extreme" cases holding "certain secret uses to be invalidating under the 'public use' [bar]"; they "do not identify any sale cases that would be overturned." Pet. 37a–38a. No legislators "in-

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[3] Helsinn cites the House Committee Report (Pet. 7), but it referenced Senate floor statements for the unrelated fact that the "'current law's grace period' 'is maintained.'" H.R. Rep. No. 112-98, at 43 & n.20 (2011).

dicat[ed] that they intended to allow parties who have exploited inventions as trade secrets for years to be able nonetheless to patent those inventions." Merges & Duffy, *supra*, at 361. Further, "[e]ven if the floor statements were intended to overrule th[e] secret or confidential sale cases," "that would have no effect here since those cases were concerned entirely with whether the existence of a sale or offer was public." Pet. 38a. Thus, Helsinn's approach to legislative history—cherry-picking floor statements while ignoring the drafting history—fails on its own terms.

D. Two centuries of this Court's precedents and the Constitution confirm that the on-sale bar is triggered by all types of sales.

Under centuries of precedent, the decision below would be correct even if the sale here were secret. This Court has repeatedly held that the Patent Act and the Constitution bar commercially exploiting inventions before patenting them.

In the leading decision, which predates the on-sale bar, this Court invalidated a patent on a process of making hose with improved joints, where the inventor had earlier authorized sales of the hose. *Pennock*, 27 U.S. at 3, 9. Although the sales did not disclose the claimed process, the Court held that where an inventor allows the invention "to be publicly sold for use, before he makes application for a patent," that "creates a disability to comply with the terms and conditions on which [the government] is authorized to grant him a patent." *Id.* at 24.

The Court relied heavily on the Constitution, which requires reading the patent laws to "promote the progress of science" and secure patents only for "*limited times*." *Id.* at 16 (Story, J.) (quoting U.S.

Const. Art. I, § 8, cl. 8). If inventors could profit from their inventions while "hold[ing] back from the knowledge of the public the[ir] secrets"—but patent them later—that "would materially retard the progress of science" and "give a premium to those who should be least prompt to communicate their discoveries.'" *Id.* at 19.

Later, in *Kendall*, this Court held that an "inventor who designedly, and with the view of applying [his invention] indefinitely and exclusively for his own profit, withholds his invention from the public, comes not within the policy or objects of the Constitution or acts of Congress." 62 U.S. at 328. Further, *Pfaff* reaffirmed *Pennock* and later cases, stating that "[a]ny attempt to use [an invention] for a profit, and not by way of experiment, for a longer period than [the prescribed grace period] before the application, would deprive the inventor of his right to a patent." 525 U.S. at 65 (quoting *Elizabeth* v. *Am. Nicholson Pavement Co.*, 97 U.S. 126, 137 (1877)). Thus, "it is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." *Pfaff*, 525 U.S. at 68 (quoting *Metallizing*, 153 F.2d at 520).

Helsinn never acknowledges that its reading of the AIA would require overruling the *Pennock* line of cases and eviscerate the Patent Act's only language preventing private commercial exploitation of inventions before patenting. See Pet. 39a–40a (discussing *Pennock*); Pet. 13a–14a (O'Malley, J.) (citing *Pfaff*'s statement that "the 'overriding' concern [of the on-sale bar] is the risk that an inventor will commercially exploit his invention beyond the statutory term"); *Continental Plastics*, 141 F.3d at 1079. Indeed, Hel-

sinn attempts to recast the on-sale bar as existing solely to protect what is "in the public domain." Pet. 27. But under this Court's longstanding view, expressed in cases such as *Pfaff*, the on-sale bar prevents exactly what Helsinn attempted to do here—extend its commercial monopoly.

Helsinn assures the Court that "under the AIA's first-inventor-to-file system," "[a]n inventor cannot secretly exploit its invention while waiting for competition to come along because the competition might beat the first inventor to the Patent Office." Pet. 24. As *Pennock* and *Metallizing* confirm, however, many inventions—especially manufacturing processes—are "easily conceal[ed]." Lemley, *supra*, at 1132. Thus, inventors "could keep their process inventions secret for years or even decades and then surface and file a patent application." *Ibid.* The prospect of that revolutionary change in the law may explain the presence of Helsinn's pro-patentee amici—most of whom are industry stakeholders who stand to gain from indefinite monopolies. Indeed, even Congressman Smith is represented by Eli Lilly's former general counsel.

"If one of [two plausible statutory constructions] would raise * * * constitutional problems, the other should prevail." *Clark* v. *Martinez*, 543 U.S. 371, 380–381 (2005). Here, allowing inventors to exploit inventions privately before patenting them would upend venerable policy and violate the Constitution.

E. Helsinn's policy arguments do not support review.

Helsinn's policy arguments would not justify certiorari even if they had merit. But they do not.

1. Helsinn says the ruling below conflicts with Congress's elimination of "territorial restrictions"

that "restricted disqualifying sales to those occurring in the United States." Pet. 25. That is no reason to think the meaning of "sale" changed. Secret overseas sales will rarely invalidate patents, and regardless the geographic limitation is unnecessary "[g]iven advances in communications technology and transportation" that provide knowledge "about activities in a foreign land." H.R. Rep. No. 110–314, at 57 (2007).

2. Helsinn complains that the ruling could harm "small" companies that rely on pre-launch confidential distribution agreements and have regulatory disclosure obligations. Pet. 5, 29–31. But even if Helsinn were small—it has over $500 million in annual revenue and products "in approximately 190 countries"[4]—such companies can avoid the bar by applying for patents for up to a year after any sale. See also Pet. 7a (O'Malley, J.). As the court below held, the "completion of Phase III studies and final FDA approval are not pre-requisites for the invention here to be ready for patenting"; and Helsinn's data "showed that the invention worked," from "the 1995 Phase II trial" onward. Pet. 47a, 51a. Thus, Helsinn's difficulty was caused by its own delay.

3. Helsinn next says the decision, by requiring searches for foreign sales, interferes with Congress's desire for "more efficient" post-grant review. Pet. 25. But Congress's purpose in amending a ground of invalidity applied primarily by courts and examiners was not driven by what would be most convenient for post-grant proceedings, and courts are not "simplistically to assume that whatever furthers" one "[statu-

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[4] https://www.helsinn.com/news-and-events/helsinn-pharmaceuticals-beijing-co-ltd-opens-office-in-shanghai-china/.

tory] objective must be the law." *Rodriguez* v. *United States*, 480 U.S. 522, 526 (1987).

4. Nor will the decision below thwart Congress's goal of "harmoniz[ing]" prior-art rules with international practice. Pet. 23. The AIA harmonized U.S. and foreign law in some ways, but not others. For example, some "foreign patent systems" lack "grace period[s]," but Congress provided "a significant number" of grace periods. Merges, *supra*, at 1032 & n.25, 1030. Finally, it harmonizes U.S. and foreign law to read the "otherwise available" clause to capture disclosures not "described in a printed publication."

CONCLUSION

For the foregoing reasons, the petition for certiorari should be denied.

Respectfully submitted.

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MAY 2018

APPENDIX

APPENDIX

NOTE: This order is nonprecedential.

United States Court of Appeals
for the Federal Circuit

HELSINN HEALTHCARE S.A.,
Plaintiffs-Appellees

v.

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Defendants-Appellants

2016-1284, 2016-1787

Appeals from the United States District Court for the District of New Jersey in Nos. 3:11-cv-03962-MLC-DEA, 3:11-cv-05579-MLC-DEA, 3:13-cv-05815-MLC-DEA, Judge Mary L. Cooper.

ON MOTION TO STAY MANDATE

Before DYK, MAYER, and O'MALLEY, *Circuit Judges*. PER CURIAM.

ORDER

The motion to stay is denied. The parties agree that granting a stay requires finding, at least, (1) "a reasonable probability that the Supreme Court will grant *certiorari*; [and] a reasonable possibility that at least five Justices would vote to reverse this Court's judgment," and (2) "a likelihood of irreparable injury" to the moving party. *Nara v. Frank*, 494 F.3d 1132, 1133 (3d Cir. 2007); *see also Doe v. Miller*, 418 F.3d 950, 951 (8th Cir. 2005); *United States ex rel. Chandler v. Cook County*, 282 F.3d 448, 450 (7th Cir. 2002) (Ripple, J., in chambers).

For the reasons set forth in the majority opinion, and in Judge O'Malley's concurrence to the denial of rehearing, the decision is a narrow one. There also has been no showing of irreparable injury. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 134 S. Ct. 1621, 1621 (2014) (Roberts, Circuit J.)

IT IS ORDERED THAT:

The motion is denied. Pursuant to Rule 41(b) the mandate will issue seven days from the date of this order.

FOR THE COURT

January 22, 2018

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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REPLY BRIEF FOR THE PETITIONER

Faced with an indefensible Federal Circuit opinion, respondents resort to comically bad misdirection. Respondents repeatedly assert that this case is a poor vehicle for the Court's review because petitioner is merely challenging the Federal Circuit's factual determination that petitioner disclosed its invention in detail to the public. But the Federal Circuit made no such determination; at most, the court noted that petitioner disclosed its invention *confidentially to its partner MGI*, and the court did so in analyzing whether petitioner's agreements with MGI invalidated its *pre-AIA* patents—a question that is not even presented here. As to petitioner's post-AIA patent, the Federal Circuit held, as a matter of law, that a

sale that does *not* disclose (or otherwise make available) the invention to the public nevertheless qualifies as prior art under the AIA's on-sale bar as long as the *fact* of the sale is known. It is that question of statutory interpretation on which petitioner seeks this Court's review, and there is no obstacle to the Court's reaching and resolving that question here.

Once their pervasive mischaracterization is taken away, respondents have little left to say. Parroting the Federal Circuit, respondents attempt to characterize the decision below as limited to the facts of this case. But a court of appeals cannot shield its opinion from this Court's review simply by including such a disclaimer, and the Federal Circuit's opinion announces a broad interpretation of the AIA's on-sale bar in Section 102(a)(1). The overwhelming support petitioner has received from diverse amici on that question of law underscores the importance of this case and highlights the urgent need for the Court's intervention.

Finally, respondents' brief is most remarkable for what it does not do: namely, defend the Federal Circuit's reasoning on the merits. There is an explanation for that omission: the Federal Circuit used a manifestly unsound method of interpretation to reach a conclusion untethered to the statutory text. While respondents devote most of their brief to the merits of the statutory-interpretation question (belying their assertions that the decision below was "narrow" and "fact-bound"), they rely not on the Federal Circuit's opinion, but on arguments made by Judge O'Malley in her subsequent effort to clean up that opinion. Respondents are of course free to advance those arguments at the merits stage if the Court grants certiorari. But no matter how it is defended, the Federal Circuit's interpretation of Section 102(a)(1) is profoundly flawed.

This case is an obvious candidate for further review, and the petition for a writ of certiorari should be granted.

1. Starting with their reformulation of the question presented, respondents repeatedly insist that this case is a poor vehicle because petitioner purportedly seeks review of "the Federal Circuit's factual conclusion that [its] sale agreement with a third party publicly disclosed its claimed invention 'in detail.'" Br. in Opp. i (quoting Pet. App. 33a); see *id.* at 16-19.

That is a wild and disingenuous contention. For starters, petitioner does not "challenge" any of the Federal Circuit's "factual conclusion[s]." Br. in Opp. 17 (emphasis omitted). As petitioner unconditionally stated in the petition, "this Court may assume that the Federal Circuit correctly determined that the MGI agreements satisfy the pre-AIA on-sale bar; it is the Federal Circuit's core holding about the effect of the AIA that demands this Court's review." Pet. 33. Petitioner is here challenging the interpretation of the AIA's on-sale bar—a question, the Federal Circuit recognized, that is "ultimately a question of law." Pet. App. 27a.

In any event, respondents' claim that petitioner disclosed the claimed formulation "in detail" to the public mischaracterizes both the record and the decision below. As to the record: respondents do not cite anywhere in the Federal Circuit that they made such a claim about petitioner's purported public disclosure. As petitioner has noted, they did not in fact do so. See Pet. 11.[1] Indeed, at oral argument below, counsel for respondents conceded that the "details of the formulation" "w[ere] not described

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[1] Respondents claim they made such an argument at page 12 of their reply brief in the Federal Circuit. See Br. in Opp. 17. But respondents made no such argument either on that page (where they were discussing the pre-AIA on-sale bar) or anywhere else in their Federal Circuit briefs.

publicly." C.A. Oral Arg. at 5:30-5:38 (Oct. 4, 2016) <tinyurl.com/c-a-argument>.

As to the decision below: the Federal Circuit made no finding that petitioner had disclosed its claimed formulation to the public. The Federal Circuit addressed the on-sale bar in two separate sections of its opinion, corresponding to the pre- and post-AIA versions of the bar. It first considered whether three patents issued before enactment of the AIA were "subject to a sale or offer for sale prior to the critical date." Pet. App. 28a. Applying its pre-AIA precedent, the Federal Circuit determined that a sale had occurred. In so doing, the court observed that petitioner had "described the [claimed] formulation in detail" *in its confidential agreements with MGI*. *Id.* at 33a. It is this statement in the pre-AIA discussion that respondents misleadingly cite in their reformulated question presented (and at least ten times in the body of their brief). See Br. in Opp. i, 1, 2, 10, 11, 14, 18, 19.

The Federal Circuit then proceeded to "address whether * * * there was [a] qualifying sale" with respect to the remaining patent in suit. Pet. App. 35a. Because that patent issued after the effective date of the AIA, the court had to confront the question presented here: namely, whether an inventor's sale of an invention to a third party obligated to keep the invention confidential qualifies as prior art under the AIA's on-sale bar. The Federal Circuit answered that question in the affirmative, concluding that Congress did not "intend[] to work * * * a sweeping change to [the Federal Circuit's] on-sale bar jurisprudence" when it enacted the AIA. *Id.* at 43a. Notably, in reaching that conclusion, the court acknowledged that the specific "dosage level[]" of palonosetron—the invention claimed by the post-AIA patent—was *not* disclosed to the public. *Id.* at 39a. The court explained that, "after the AIA, if the existence of the sale is

public, *the details of the invention need not be publicly disclosed* in the terms of sale." Pet. App. 43a (emphasis added).[2]

Respondents' contention that the Federal Circuit found the details of the invention were publicly disclosed is thus entirely incorrect. To the extent that petitioner made a "detailed" disclosure about its invention, it made that disclosure *confidentially to MGI*, not to the public at large. That is a feature, not a bug, of this case: the legal question that this case presents is whether the sale of an invention to a third party that is obligated to keep the details of the invention confidential qualifies as prior art that triggers the AIA's on-sale bar in Section 102(a)(1). There is no factual dispute that could serve as an obstacle to the Court's resolving that legal question; the Federal Circuit correctly understood the facts, but simply got the law wrong.[3]

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[2] Respondents emphasize the government's statement at oral argument that it would not have "heartburn" if the Federal Circuit "conclude[d] that this was in fact a sale that made the invention available to the public." Br. in Opp. 18. As discussed above, however, the Federal Circuit did not reach any such conclusion; rather, it concluded that petitioner's sale to MGI triggered the AIA's on-sale bar even though the invention was *not* disclosed to the public.

[3] Respondents assert that petitioner "affirmatively disclaimed the position that an invalidating offer requires disclosure of the details of the invention." Br. in Opp. 18 (internal quotation marks and alterations omitted). That is also incorrect. Petitioner noted that it had "never contended that an invalidating offer requires disclosure of 'the details of the * * * invention,' and in fact argued * * * that the AIA left the inherency doctrine intact." C.A. Pet. for Reh'g 10. In so noting, petitioner was merely reaffirming the unremarkable proposition that, under the doctrine of inherency, the *public sale* of a product embodying a claimed invention may trigger the on-sale bar, regardless of whether it is accompanied by a disclosure of the details making up the invention. But the invalidating sale must still be made "to the

2. In an effort to diminish the importance of this case, respondents insist that the decision below is "narrow" and limited to the "circumstances involved" here. See Br. in Opp. 13-16. That contention is untenable.

a. The reasoning of both the Federal Circuit's opinion and Judge O'Malley's subsequent concurring opinion fatally undercuts respondents' contention. While the Federal Circuit and Judge O'Malley (in an apparent attempt to shield the court's decision from review) each insisted that the decision was narrow, both painted with broad brushes in their legal analyses. The Federal Circuit reasoned that the AIA did not "work * * * a sweeping change to [the court's] on-sale bar jurisprudence," and ultimately held that, "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." Pet. App. 43a. Judge O'Malley likewise characterized the Federal Circuit's opinion as standing for the proposition that the AIA "did not change" the on-sale bar. *Id.* at 3a-4a. In light of those broad statements, respondents cannot seriously contend that the decision below was somehow limited to the facts of this case; the decision plainly embodies a legal conclusion about the interpretation of the AIA's provision defining prior art.

Respondents further contend that the decision below does not affect the PTO's guidance to its examiners because its guidelines "state[] only that a secret sale or use activity does not qualify as prior art." Br. in Opp. 18 (internal quotation marks and citation omitted). But that is a misrepresentation of the guidelines. The PTO expressly instructed its examiners that sales "among individuals having an obligation of confidentiality to the inventor"—

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public" within the meaning of the AIA; the sale to MGI here plainly was not.

such as petitioner's sale to MGI—do not qualify as prior art under the AIA's on-sale bar. 78 Fed. Reg. 11,075 (Feb. 14, 2013). The impact of the decision below on the PTO's guidelines is reason enough to grant the petition—especially because the government has already taken the position that petitioner should prevail under the correct interpretation of Section 102(a)(1). See Gov't C.A. Br. 4.

b. Perhaps the strongest indication of the broader significance of the decision below is the vast array of amici that have filed briefs supporting the petition. Petitioner's amici include representatives of small manufacturers and innovators, individual intellectual-property owners, large pharmaceutical manufacturers, midsize biotechnology companies, and patent attorneys; organizations dedicated to the study of intellectual-property law and policy; and even Representative Lamar Smith, the eponymous sponsor of the AIA.

That diverse group of amici shares a common concern: that the decision below misconstrues the AIA and jeopardizes innovators' ability to invest in research and bring new products to market. As Representative Smith explained, the new statutory language "leaves no room for doubt" that confidential sales (such as petitioner's to MGI) are no longer prior art. Rep. Smith Br. 4. The PTO confirmed that interpretation in its guidelines, and companies and their investors have allocated resources in reliance on it. See PhRMA Br. 6.

The decision below upends the patent community's shared understanding of the AIA. And the community has responded in force, making clear that the decision below will not only jeopardize patent portfolios but chill the very innovation the patent system is designed to protect. See, *e.g.*, U.S. Inventor Br. 7; BIO Br. 1-5. That concern is especially acute for small companies and inventors, which are the engine of innovation in this country and are

increasingly responsible for the development of new drugs. See U.S. Inventor Br. 6-7; BIO Br. 1-5, 7. Small inventors are dependent on partnerships and risk-sharing agreements such as the one between petitioner and MGI to bring their inventions to market.[4]

In addition, small and large companies alike must decide whether to pursue a new drug years before the drug will hit the market. The decision whether to proceed with the development of a drug often depends on the expected strength of the drug's patents. See PhRMA Br. 5-6. Uncertainty about the validity of the patents naturally impedes that development. But such uncertainty is just what the Federal Circuit's decision has sown: more than one million patents have issued since the AIA's revised on-sale bar took effect, and many of those patents are now in question. See *id.* at 3.

What is more, as amici have explained, the Federal Circuit's decision is directly contrary to the AIA's stated goal of harmonizing American patent law with the law of other jurisdictions. If the decision below is allowed to stand, the United States would be the only industrialized country to invalidate patents on the basis of "secret" prior art. See Rep. Smith Br. 21; Gov't C.A. Br. 10. Indeed, the decision below actually *expands* the scope of prior art beyond pre-AIA standards: while sales and uses could not serve as prior art before the enactment of the AIA unless

---

[4] Respondent Teva Pharmaceutical Industries—the largest generic drug manufacturer in the world, with over $22 billion in annual revenue—chastises petitioner for characterizing itself as a "small" company, citing petitioner's annual revenue of over $500 million. See Br. in Opp. 33. Petitioner, however, was able to grow to its current size only because it shared the risks and pooled the resources needed to develop Aloxi with its partner MGI; petitioner would otherwise have been unable to bring Aloxi, its most commercially successful drug, to market.

they occurred "in this country," see 35 U.S.C. 102(b) (2006), the AIA eliminated that restriction, with the result that, under the decision below, even confidential transactions that occurred outside the United States could qualify as prior art. See Pet. 25.

In light of the array of amici, there can be no doubt that the Federal Circuit's decision is sowing considerable uncertainty about the interpretation of the on-sale bar in Section 102(a)(1)—one of the most important provisions defining the scope of patent protection under the AIA. That decision warrants the Court's immediate review.

3. Respondents dedicate the majority of their brief to an assortment of merits arguments. See Br. in Opp. 4-9, 19-34. Petitioner has already addressed many of those arguments in its petition for certiorari, and it will address them in more detail at the appropriate time if the Court grants review. For present purposes, just a few additional points are warranted here.

a. Respondents first make a series of textual arguments. See Br. in Opp. 19-27. Those arguments are nowhere to be found in the decision below, and petitioner has anticipated virtually all of them in the petition. For example, respondents argue that applying the requirement that a sale make an invention "available to the public" to "public use[s]" would create redundancy. *Id.* at 23. The Federal Circuit, however, has long considered certain secret uses to be invalidating "public use[s]." See Pet. 17-18. Respondents summarily dispute that proposition, see Br. in Opp. 23, but even the decision below acknowledged that "[Federal Circuit] precedent had held certain secret uses to be invalidating under the 'public use' prong of [Section] 102(b)." Pet. App. 37a-38a.

b. Respondents devote considerable attention to the historical meaning of "on sale." See Br. in Opp. 30-32. That is a sleight of hand. The question presented by this

case is not which transactions qualify as "sales" under pre-AIA precedent, but whether a confidential commercial "sale" qualifies as prior art after the AIA. The text of the AIA—not pre-AIA precedent—answers that question.

c. Respondents' reliance on pre-AIA authorities such as *Metallizing Engineering Co.* v. *Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), see Br. in Opp. 7-8, is similarly unavailing. The AIA's authoritative committee reports—which respondents ignore in their one-sided rendition of the legislative history, see *id.* at 8-9, 27-30—make clear that Congress intended to overturn cases such as *Metallizing* by eliminating "secret sales" from the definition of prior art. See Pet. 7 (citing House and Senate Reports). In their floor statements, the AIA's sponsors were even more explicit: Senator Leahy explained that the statute would "do away with precedent under current law that private offers for sale or private uses * * * may be deemed patent-defeating prior art," 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011), and Representative Smith agreed that, "contrary to current precedent, * * * an action must make the patented subject matter 'available to the public' before the effective filing date," 157 Cong. Rec. H4429 (daily ed. June 22, 2011).

Respondents attempt to tie the pre-AIA lower-court authorities on which they rely to this Court's decision in *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1 (1829). See Br. in Opp. 4-6. But that decision unequivocally supports petitioner, not respondents. In *Pennock*, this Court explained that, "[i]f the public were already in possession and common use of an invention," then "there might be sound reason for presuming[] that the legislature did not intend to grant an exclusive right to any one." 27 U.S. (2 Pet.) at 23. The Court thus emphasized that a sale *to the public* could invalidate a patent. See *id.* at 23-24. That reasoning

is entirely consistent with petitioner's interpretation of the AIA, under which a public sale may trigger the on-sale bar. See p. 5 n.3, *supra*.

We could go on. For now, however, respondents' extended discussion of the merits only confirms the need for this Court's intervention. The Federal Circuit's decision has created tremendous uncertainty in the patent community on an exceptionally important question of statutory interpretation. This Court's review is necessary to resolve that uncertainty and to correct the Federal Circuit's deeply flawed decision.

* * * * *

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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MAY 2018

No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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INTEREST OF AMICUS CURIAE

The American Intellectual Property Law Association ("AIPLA") is a national bar association of approximately 13,500 members who are primarily lawyers engaged in private and corporate practice, in government service, and in the academic community. AIPLA's members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

AIPLA has no stake in any of the parties to this litigation or in the result of this case.[1]

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[1] In accordance with Supreme Court Rule 37.6, AIPLA states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than AIPLA and its counsel. Specifically, after reasonable investigation, AIPLA believes that (i) no member of its Board or Amicus Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to the litigation in this matter, (ii) no representative of any party to this litigation participated in the authorship of this brief, and (iii) no one other than AIPLA, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

AIPLA has no stake in the parties to this litigation or in the result of this case, other than its interest in the correct and consistent interpretation of the laws affecting intellectual property.[2]

SUMMARY OF ARGUMENT

This case requires Supreme Court review to resolve the confusion created by the Federal Circuit's failure to give effect to a revision of the "on sale" doctrine, which Congress enacted to bring transparency, objectivity, and predictability to the patent system.

Under the 1952 Patent Act, the "on sale" doctrine prevented an inventor from obtaining a patent on an invention that was commercially sold more than a year before the application was filed. Its purpose was to incentivize prompt filings of patent applications and to discourage the commercial exploitation outside of the patent term.

When the America Invents Act ("AIA") replaced our "first to invent" patent system with a "first inventor to file" patent system, it did so to harmonize U.S. law with patent systems around the world and to incentivize prompt filing of patent applications, thereby promoting disclosure and accelerating innovation. Its changes to the "on sale" provision

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[2] AIPLA has the consent of the parties to file this amicus brief, pursuant to Supreme Court Rule 37.3(a), based on the blanket consents filed with this Court by Petitioner on March 13, 2018 and by Respondent dated March 19, 2018. Pursuant to this Court's Rule 37.2(a), Counsel of Record for Petitioner and Respondent received notice of AIPLA's intent to file this brief on March 15, 2018.

implemented those objectives by imposing a "public availability" requirement not only on the fact of the sale transaction itself, but also on subject matter of the sale transaction, i.e., the "claimed invention." These changes abandoned the forfeiture model of the former on-sale provision, which had become a trap for unwary inventors, and adopted a pro-disclosure model which is based on prior art categories that serve as conditions of patentability.

Although the meaning of "available to the public" may need to be developed on a case-by-case basis for different types of inventions, any such questions cannot justify turning a blind eye to the express language of the statute. That language, at a minimum, requires that the "claimed invention"—with all of its claim limitations—be "available to the public. Moreover, the decision below will convert what should be a legal issue in most cases into a fact-intensive issue in many cases. This will not only jeopardize the prior investment in inventions claimed in the patent(s)-in-suit, but will also increase the time and expense required for discovery, motion practice, trial, and appellate review.

This Court's intervention is urgently needed to ensure that the statutory mandate is observed and that the congressional objectives of the AIA are fulfilled.

ARGUMENT

I. The Court Should Review This Case To Restore The Statutory Definition of Prior Art.

This Court should review this case because the Federal Circuit's interpretation of the AIA's "on sale" provision distorts the meaning of prior art by undermining the statutory requirement of "public availability," a feature central to the AIA's purpose of improving the efficiency and predictability of the U.S. patent system.

According to the House Report, "[t]he Act . . . simplifies how prior art is determined, provides more certainty, and reduces the cost associated with filing and litigating patents." H.R. REP. NO. 112-98, at 42 (2011). *See also id.* at 40 (the "legislation is designed to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs."). The AIA § 102(a)(1) requirement that claimed inventions be publicly available to qualify as prior art simplifies the decision to pursue patent protection by minimizing the cost to investigate whether the invention has been publicly used or sold. This requirement also lessens discovery in litigation by eliminating an otherwise fact-intensive inquiry into whether the claimed invention was subject to any potentially invalidating uses or sales.

A. The Amended Text Of The AIA Was Erroneously Interpreted By Federal Circuit.

As amended, section 102(a)(1) provides as follows:

> (a) Novelty; Prior Art.—A person shall be entitled to a patent *unless*—
>
> > (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention....

35 U.S.C. § 102(a)(1) (2012) (emphasis added). Inventors cannot obtain patents "unless" they can overcome the prior art, making the definition of prior art fundamental to the patent system.

Congress passed the AIA in 2011 as the first major reform of U.S. patent law since the 1952 Patent Act, transforming the former "first-to-invent" system into the current "first-inventor-to-file" system. The AIA revised the language of §102(b) of the 1952 Act and moved it into a new § 102(a)(1), as follows:

> (a) Novelty; Prior Art.—~~Conditions for patentability; novelty and loss of right to patent~~ A person shall be entitled to a patent unless—
>
> > (1) the claimed invention was patented, ~~or~~ described in a printed publication, ~~in this or a foreign country~~ or in public use, ~~or~~ on sale, ~~in this country,~~ or otherwise available to the public before the

> effective filing date of the claimed invention; ~~more than one year prior to the date of the application for patent in the United States~~....

35 U.S.C. § 102(a)(1) (2012). The critical differences between the pre- and post-AIA versions of this language include:

> (1) the title is changed to strike "loss of right to patent" and to insert "Prior Art," reflecting the provision's focus on defining prior art rather than forfeiture events;
>
> (2) "claimed" now appears before "invention,"
>
> (3) "in this country" no longer appears after "in public use or on sale;"
>
> (4) "or otherwise available to the public" was added following the list of patent-defeating prior art; and,
>
> (5) "more than one year prior to the date of the application for patent in the United States" was changed to "before the effective filing date of the claimed invention."[3]

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[3] The decision below reveals a misunderstanding of the AIA by referring in several places to the patent's "critical date." Pet. App. at 19a, 20a, and 25a-27a. "Critical date" refers to the date more than one year before the filing of a patent application under the 1952 Act to determine the grace period for such filings. *Monon Corp. v. Stoughton Trailers, Inc.*, 239 F.3d 1253, 1257 (Fed. Cir. 2001). However, the relevant term under § 102(a)(1) is "effective filing date," defined at 35 U.S.C. § 100(i) as "the actual

The decision below failed to give full effect to these revisions, despite the plain language of § 102(a)(1).

The AIA defines "claimed invention" as "the subject matter defined by a claim in a patent...." 35 U.S.C. § 100(j). The subject matter of a claim is defined by all of the claim's limitations. The statute places the "claimed invention" in the prior art only if it was on sale "or otherwise available to the public" before the patent's "effective filing date." The term "otherwise" means "in a different way or manner" (*Merriam-Webster's Collegiate Dictionary*, at 823 (10th Ed. 1998)). Thus, the "claimed invention" is prior art only *where it is made available to the public, by sale or otherwise*. By not requiring the "claimed invention," with all of its limitations, to be "available to the public," the decision below effectively removed both terms—"claimed"[4] and "otherwise"—from the statute. *E.g.*, *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.").

The USPTO agrees with this plain reading of § 102(a)(1). In its examiner guidelines, the USPTO has stated that "otherwise available to the public" is a "catch-all" provision that focuses on whether the disclosure was "available to the public" rather than

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filing date of the patent or the application for the patent containing a claim to the invention" or "the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority...."

[4] The decision below acknowledges that at least one element of the claimed invention, the dosage, was not disclosed to the public before the effective filing date of the patent. Pet. App. at 24a.

whether it falls within another prior art category defined by the statute. 78 Fed. Reg. 11059, 11075 (2d col.). Under those guidelines, secret sales do not qualify as prior art, only public ones do, and this applies to all documents and activities itemized in § 102(a)(1). *Id.* at 11062 (2d col.); *see also* Brief for the United States as *Amicus Curiae* at 5, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017), No. 16-1284 ("Brief of USA"). The USPTO's reasonable interpretation is entitled to deference. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844, 865-66 (1984).

The concurring opinion on denial of rehearing *en banc* argued that under the "last antecedent" doctrine "to the public" modifies only "otherwise available." Pet. App. at 11a. "Otherwise available to the public" is one phrase, however, and cannot be artificially divided in this manner. Moreover, "otherwise available to the public" is immediately followed by "before the effective filing date." "Before the effective filing date" indisputably applies to all the listed forms of prior art – patents, printed publications, etc. But "or otherwise available to the public" *is actually part of the same phrase, not even separated by a comma* from "before the effective filing date." Therefore, "or otherwise available to the public" must also apply to all the listed forms of prior art, including when the claimed invention is "on sale."

B. The Federal Circuit Misapplied Pre-AIA Law To Interpret The New AIA Text.

The Federal Circuit relied on pre-AIA law to construe the AIA's § 102(a)(1) because it felt Congress's intent to change the law was not sufficiently clear. Pet. App. at 11a (citing *Dir., OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 321 (1983)). In *Perini*, the Court considered whether an amendment to the Longshoremen's and Harbor Workers' Compensation and Health Act overruled this Court's decision in *Calbeck v. Travelers Ins. Co.*, 370 U.S. 114 (1962). *Calbeck* held that Congress did not incorporate a "maritime but local" exception to compensation into the Act. The Court wrote: "Surely, if Congress wished to repeal *Calbeck* and other cases legislatively, it would do so by clear language and not by removing from the statute the exact phrase that *Calbeck* found was responsible for continued emphasis on the 'maritime but local' doctrine." *Id.* at 321. Thus, the Court did not hold that Congress can only repeal a case legislatively by clear language.

In this case, Congress's intent to impose a public availability standard for prior art is clear from the express "or otherwise available to the public" language of the statute. The changes to § 102(a)(1) are analogous to the changes to 28 U.S.C. § 1367 which the Court considered in *Exxon Mobil Corp. v. Allapattah Servs.*, 545 U.S. 546 (2005). In *Exxon*, the Court addressed whether an amendment to § 1367 overruled *Zahn v. Int'l Paper Co.*, 414 U.S. 291 (1973). Rejecting an argument that the amended statute was ambiguous, so the Court should consider other canons

of construction, the Court wrote: "We can reject this argument at the very outset simply because § 1367 is not ambiguous." *Id.* at 567. Earlier in the opinion, the Court wrote:

> No sound canon of interpretation requires Congress to speak with extraordinary clarity in order to modify the rules of federal jurisdiction within appropriate constitutional bounds. Ordinary principles of statutory construction apply. In order to determine the scope of supplemental jurisdiction authorized by § 1367, then, we must examine the statute's text in light of context, structure, and related statutory provisions.

Id. at 558. Section 102(a)(1), after its amendment by the AIA, is likewise unambiguous. Congress is no more required to speak with "extraordinary clarity," if that were possible, when amending it than when amending § 1367. The Court should construe § 102(a)(1) consistent with its express requirement that prior art must be "available to the public."

The decision below also erred by construing § 102(a)(1) according to pre-AIA case law because, as illustrated in detail above, post-AIA § 102(a)(1) includes at least five major changes to pre-AIA § 102(b). Congress is presumed to adopt the prior interpretation of a statute only "when it re-enacts a statute without change." *Lorilland v. Pons*, 434 U.S. 575, 580 (1978). Congress did not re-enact § 102 "without change," so it cannot be presumed to have adopted any prior interpretations.

The plain language of § 102(a)(1) requires that, to qualify as prior art, the "claimed invention" must be "available to the public." Even if the language of § 102(a)(1) were ambiguous, however, the legislative history would unambiguously impose a public availability standard on prior art. The House Report on the AIA explains that "[p]rior art will be measured from the filing date of the application and will typically include all art that *publicly exists* prior to the filing date, other than disclosures by the inventor within 1 year of filing." H.R. REP. NO. 112-98, at 42 (2011) (emphasis added). The House Report continues that "the phrase 'available to the public' [was] added to clarify the broad scope of relevant prior art, *as well as to emphasize the fact that it must be publicly accessible*." *Id.* at 42-43 (emphasis added). This legislative history confirms the statutory language that all prior art, including sales, must make the invention available to the public. The decision below ignores this Report and incorrectly states that this reading of the statute depends upon "floor statements made by individual members of Congress." Pet. App. at 36a.

In short, this case presents an important issue of the proper definition of prior art, which is fundamental to the patent system.

C. Secret Prior Art and The Incentives Of The First-Inventor-To-File System.

Incentives for prompt and complete disclosure of inventions are necessary to the bargain between the

inventor, who receives exclusive rights, and the government, which receives the disclosure. The incentive for the inventor to file promptly is particularly important to the government and the public where an invention can be kept secret while it is being commercialized. Under the first-to-invent system, inventors had a compelling incentive to defer filing for a patent. The first inventor could extend its exclusive use of the invention by waiting to seek a patent until the invention became public, through either another person's (1) public disclosure of the invention or (2) filing a patent application on the invention.

Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co., 153 F.2d 516 (2d Cir. 1946), is the seminal decision on secret prior art. In that case, the issue was the secret use of a process before the grace period and the sale of the unpatented products of that process. One basis for the secret use to be prior art was that the patent owner was benefitting from both trade secret and patent protection. As Judge Hand wrote, "it is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; *he must content himself with either secrecy, or legal monopoly*." *Id.* at 520 (emphasis added).[5]

Under the first-to-invent system, an inventor who used or sold an invention more than a year before

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[5] In response to comments that it should preserve the rule of *Metallizing Engineering* and related doctrines despite the AIA, the PTO wrote "some of the purposes ascribed to these doctrines in case law appear to be ill-suited to or inconsistent with the AIA." 78 Fed. Reg. 11059, 11075 (3d col.).

filing a patent application was at risk of losing the right to the patent. The harm of that loss, however, far outweighed the benefit of encouraging prompt filing. "The current forfeiture doctrines have become traps for unwary inventors and impose extreme results to no real purpose." 157 Cong. Rec. S1371 (March 8, 2011) (1st col.) (Remarks of Senator Kyl discussing § 102 of S. 23, which was identical to § 102 of House bill 1249 that became the AIA). Individual and/or unsophisticated inventors forfeited their right to a patent because of limited and private uses that did not disclose the claimed invention to the public.[6] "The only effect of rulings like these is to create heavy discovery costs in every patent case, and to punish small inventors who are unaware of the pitfalls of the [pre-AIA section 102(b)]." *Id.*[7]

As noted above, with the enactment of the AIA, the United States joined the rest of the industrialized world in having a system which awards patents to the first inventor to file an application covering the claimed invention. Under a first-inventor-to-file standard, the reasons for barring an inventor from

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[6] As examples, the Congressional Record cites *Egbert v. Lippman*, 104 U.S. 333 (1881) (corset spring inherently hidden from view and given to only one woman held to be "in public use"), *Beachcombers Int'l, Inc. v. Wildewood Creative Prods., Inc.*, 31 F.3d 1154, 1159-60 (Fed. Cir. 1994) (improved kaleidoscope "in public use" because shown to guests at private party), and *JumpSport, Inc. v. Jumpking, Inc.*, 191 Fed. Appx. 926 (Fed. Cir. 2006). *See* 157 Cong. Rec. S1371 (1st & 2d col.). All citations to the Congressional Record in this brief are to volume 157 of the daily edition.

[7] *See also* cases discussed at note 12 *supra*.

seeking a valid patent after a prolonged period of secret commercial use disappear:

> There is no need to also require forfeiture of patents simply because the inventor has made some use of the invention that has not made the invention available to the public. And the current on-sale bar [of pre-AIA section 102(b)] imposes penalties not demanded by any legitimate public interest. There is no reason to fear "commercialization" that merely consists of a secret sale or offer for sale but that does not operate to disclose the invention to the public.

Id. The first-inventor-to-file system provides a strong incentive to file promptly for patent protection and thereby disclose the invention to the public. Every day an inventor delays filing a patent application, even if it adds another day's profit from the invention, risks losing twenty years of patent protection to another inventor who files first.

Finally, by maintaining an inventor's right to obtain patent protection even after a confidential sale of an invention, §102(a)(1) provides a continuing incentive to disclose an invention. Once the invention has been disclosed in a patent application, others can improve it to progress the useful arts. On the other hand, if Congress had not protected an inventor's right to a patent despite a secret sale, inventors would have a continuing incentive to maintain and use their invention in secret. Encouraging such secrecy would have the effect of retarding rather than promoting the

progress of the useful arts. Thus, instead of discouraging disclosure by maintaining the old forfeiture provisions, Congress "provide[d] ample incentive for an inventor to enter the patent system promptly" in the AIA "[b]y adopting the first-to-file system." *Id.*

II. The "Public Availability" Requirement Reduces Prosecution, Transaction, and Litigation Risk and Expense Created By Secret Sales

Courts have a "duty to construe statutes, not isolated provisions." *Graham County Water and Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 290 (2010) (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 568 (1995)).[8] The introduction of the "public availability" requirement to the on-sale doctrine is consistent with the underlying purpose of the AIA to transform the U.S. patent system "from one of non-transparency, subjectivity, unpredictability and excessive complexity, to one that will operate with near-complete transparency, objectiveness, predictability and simplicity...." *See* Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 9 (2012) ("Armitage"). For example, the AIA eliminated fact-sensitive, discovery-intensive, and subjective elements such as the "best mode" defense from pre-AIA § 112[9] and "deceptive intention" from

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[8] The Federal Circuit erred by focusing on only two words, "on sale," not even an isolated provision, let alone the entire statute.

[9] *Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1314 (Fed. Cir. 2002) (whether best mode existed is subjective based on

pre-AIA §§ 116, 251, 253, 256, and 288. The AIA also added new § 257 on supplemental examination to address the fact-sensitive, discovery-intensive, and subjective inequitable conduct defense.[10]

Under pre-AIA § 102(b), interested parties cannot readily determine whether a patent will be subject to a public use or on-sale invalidity defense. This uncertainty affects decisions throughout a patent's lifecycle. Should a patent be pursued, licensed, acquired, or litigated? The answers to these questions depend on the answers to several others. Had there been a secret use in the U.S. more than a year prior to the filing of the patent application? Had the inventor (or a third party) engaged in some arguable sales activity in the U.S. more than one year before the application was filed? Was the invention "ready for patenting" at the time? If so, was that activity experimental? These questions can only be answered after completing extensive document review and multiple interviews or depositions.

The experimental use exception to the on-sale bar is particularly fact sensitive, requiring consideration of the following factors:

> (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether

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"what the inventor actually believed at the time the application was filed").

[10] *See* Armitage, 40 AIPLA Q.J. at 9.

> records of the experiment were kept, (8) who conducted the experiment, . . . (9) the degree of commercial exploitation during testing[,] . . . (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.

Allen Eng'g, Inc. v. Bartell Indus., Inc., 299 F.3d 1336, 1353 (Fed. Cir. 2002). When the on-sale bar is at issue, the parties naturally will seek documents and testimony bearing on all these factors. In patent prosecution or transactions, this additional due diligence adds cost and risk and, in litigation, the discovery often triggers disputes that require court intervention, extends the length of any trial, and creates a voluminous record for appeal.

Because invalidating sales under AIA § 102(a)(1) are no longer confined to those taking place "in this country," the decision below will even increase due diligence and discovery expenses for alleged sales that took place overseas. Parties to transactions or litigation may have to seek documents or take interviews or depositions or other discovery all over the world to develop the facts surrounding an alleged public use or secret sale.

By reducing the amount of due diligence or discovery required to determine if a sale is prior art under §102(a)(1), Congress created the certainty

required for parties investing in patent applications, pursuing licenses or acquisitions, and evaluating patent litigation. Resources that had been directed to investigations or litigation under the prior law can now be directed to enhancing innovation (*i.e.*, furthering progress in the useful arts). *See, e.g.*, 157 Cong. Rec. S5320 (daily Sept. 6, 2011) (2d col.); *see also id.* (1st col.) ("Also, for businesses seeking legal certainty, our current system can be a nightmare.... Given that both the product developer and competitor can rely on their own secret documents that the other side will not see until litigation over the patent commences, neither of these two parties can gain a clear picture of whether a patent is valid without years of litigation and millions of dollars of discovery and other litigation costs."). Being able to assess patentability from publicly accessible information is essential for making timely and prudent business decisions, both for patentees and for potential infringers.

The costs to obtain and enforce a patent are not trivial, as demonstrated in biannual AIPLA surveys of its members. The 2017 Report of the Economic Survey ("2017 Report") shows that the average cost for an original application of minimal complexity ranged from $5,593 to $11,679, depending on the geographic area. The average cost for a "relatively complex biotechnology/chemical" application ranged between $9,050 and $14,750. Of course, the cost of the application is just the beginning. The applicant must pay counsel to review and respond to Office Actions, prepare Information Disclosure Statements, and undertake other activities. Petitioner states that over one million patents have been issued under the AIA.

Petition for Writ of Certiorari ("Petition") at 14. The minimum average investment in these patents at the 2017 rates is between $5.5 billion and $14.75 billion and the actual investment is undoubtedly much more. The decision below exposes that investment to additional risk, risk that was unanticipated in light of the PTO's interpretation of § 102(a)(1). *See* text at pp. 7-8 *supra*.

Not surprisingly, the costs of patent litigation are much higher. For cases with over $25 million at stake, the average cost through trial and appeal ranges from $2.125 million to over $5.467 million, depending on the location. Congress was understandably concerned with lowering these numbers by limiting prior art to publicly available references, or in other words, eliminating costly discovery into confidential sales.

Moreover, old "public use" and "on-sale" law led to many outcomes that defied logic and no longer serve any policy objective under the AIA.[11] As one commentator wrote:

> It is one of the ironies of the pre-AIA patent law that § 102(a)'s invalidating "use" must make an invention accessible to the public, while § 102(b)'s "public use" can include private uses that are not accessible to the public. *See Woodland Trust*, 148 F.3d at 1370; *Trading Tech. Int'l, Inc. v. eSpeed, Inc.*, 507 F. Supp. 2d 883, 893 (N.D. Ill. 2007), *aff'd*, 595 F.3d 1340 (Fed. Cir. 2010) (finding that the secret commercial use

[11] *See, e.g.*, the cases cited in notes 6, *supra*, and 12, *infra*.

> of an inventor's own invention may constitute public use).

Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 450 n.97 (2012). The PTO also recognized that its interpretation of §102(a)(1), combined with the grace period of post-AIA §102(b), "avoids the very odd potential result that the applicant who had made his invention accessible to the public for up to a year before filing an application could still obtain a patent, but the inventor who merely used his invention in secret one day before he filed an application could not obtain a patent." 78 Fed. Reg. at 11062 (Feb. 14, 2019). Treating secret sales as prior art would lead to that "very odd potential result." If the Court retains the pre-AIA construction of "on sale," it will extend the uncertainty and oddity of the old interpretation. Further, it will undermine Congress's objective to make the outcome of patent prosecution and litigation more predictable at the outset and reduce the related expenses.

The decision below will perpetuate the fact-intensive approach of pre-AIA case law. It states: (1) "the AIA did not change the statutory meaning of 'on sale' ***in the circumstances involved here***," Pet. App. at 20a (emphasis added); and (2) "[w]e do not find that distribution agreements will always be invalidating under § 102(b) [*sic* – 102(a)]. We simply find that this particular Supply and Purchase Agreement is." Pet. App. at 43a. The opinion concurring in the denial of rehearing *en banc* also portrayed the decision as fact-specific. Pet. App. at 5a. Thus, the decision below will continue to require

substantial time and expense for investigation, discovery, motion practice, trial, and appeal to define the specific sales arrangements that do or do not constitute prior art. This result is contrary to the congressional intent "to reduce the costs associated with filing and litigating patents." *See* H.R. REP. NO. 112-98, at 42.

The revision of § 102(a)(1) to introduce the requirement of "public availability" for the sale of an invention to qualify as prior art was consistent with the AIA's overall shift towards objectivity, predictability, and efficiency. The change brought the on-sale doctrine into conformity with the public nature of the other prior art items listed in the statute (patents and printed publications). Further, it overruled the cases that had allowed the on-sale doctrine to reach "any commercial use, public or not, even where the subject matter of the offer is unavailable for purchase by members of the public" and thereby barred patentability.[12] *Gen. Elec. Co. v.*

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[12] For example, *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357-1358 (Fed. Cir. 2001) (refusing to recognize a "supplier" exception to the on-sale bar); *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998) (finding an inventor's own secret commercial use before the grace period may be a public use barring patentability); *Evans Cooling Systems, Inc. v. General Motors Corp.*, 125 F.3d 1448, 1454 (Fed. Cir. 1997) (refusing to create an exception to the on-sale bar for sales before the grace period that result from a misappropriation of the invention by a third party); *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946) (applying the on-sale bar to sales before the grace period of unpatented products made by the secret use of the patented process); *Hall v. Macneale*, 107 U.S. 90, 96 (1883) (finding the sale of "burglar-proof" safes to be a public use despite testimony that technology was completely concealed within the safe).

United States, 654 F.2d 55, 61 (Cl. Ct. 1981). The change is consistent with the other amendments made to U.S. patent law in the AIA, all of which eliminated subjective, fact-sensitive inquiries.

III. Other Policy Considerations Support The Public Availability Requirement.

Several policy considerations support §102(a)(1)'s exclusion of secret sales from the prior art. Some of those considerations have been discussed above, such as (1) the first-inventor-to-file standard provides ample incentive to file patent applications promptly; (2) eliminating secret sales as a forfeiture of patent rights provides a continuing incentive to file a patent application, facilitating continued progress in the useful arts; and, (3) the needs for increased business certainty and reduced litigation expenses.

Congress also imposed this public-availability requirement on prior art to protect U.S. businesses from having their inventions stolen or patents invalidated by unscrupulous foreign competitors. Senator Kyl stated:

> Finally, *validating prior art will depend on publicly accessible information*, not private activities that take place, for example, in a foreign land. As a result, it will be impossible for a third party who derived the invention from a U.S. inventor's public disclosure or patent application to steal the invention or sabotage the U.S. inventor's patent.

157 Cong. Rec. S5320 (Sept. 6, 2011) (3d col.) (emphasis added). To allow secret sales anywhere in the world to serve as prior art would facilitate the theft of U.S. inventions, contrary to Congress's expressed intent. The Court can protect U.S. inventors against this risk by granting review and reinstating the public availability requirement for prior art mandated by the plain language of § 102(a)(1).

A final consideration is that upholding Congress's removal of secret sales as a forfeiture of patent rights will assist in achieving a greater level of substantive harmonization of patent laws among the U.S., Europe, Japan, and other countries. AIPLA is not aware of any foreign country that uses a first-inventor-to-file system and also includes secret sales as a basis for a loss of right to a patent.[13] The House Report on the AIA cites "the value of harmonizing our system for granting patents with the best parts of other major patent systems throughout the industrialized world for the benefit of U.S. patent holders" as one of the motivations for the bill. H.R. REP. NO. 112-98, at 39. Conversely, maintaining secret sales as a basis for losing the right to a patent would detract from Congress's goal of further harmonizing U.S. patent law with that of other major industrialized nations.

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[13] The Government made a similar assertion in its amicus brief below. Brief of USA at 10. The fact no other country considers secret sales to be prior art confirms that the adoption of a first-inventor-to-file system provides a sufficient policy incentive to ensure early disclosure.

CONCLUSION

The Court should grant the Petitioner's writ to review this exceptionally important issue under the America Invents Act.

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In the Supreme Court of the United States

HELSINN HEALTHCARE S.A.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA IN SUPPORT OF PETITIONER

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INTEREST OF THE AMICUS CURIAE

The Bar Association of the District of Columbia ("BADC") respectfully submits this brief as *amicus curiae* in support of petitioner.[1]

Founded in 1871, the BADC, a non-profit organization, is one of the oldest bar associations in the nation. The BADC and its members have a proud history of working closely with the judiciary, courts, the DC council, and the U.S. Congress on the administration of justice. The Intellectual Property Section ("IP Section") of the BADC draws its membership from individuals in government, industry, and private practice having an interest in intellectual property law including patent, trademark, and copyright law. The IP Section has a substantial interest in the adjudication of significant issues related to patent laws and submits *amicus curiae* briefs only when issues of significant importance arise. This case presents such an important issue. The Federal Circuit's interpretation of the Leahy-Smith America Invents Act ("AIA") and its failure to recognize the change that the AIA made to the on-sale bar will have an impact on many of the more than one million

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[1] This brief is presented by The Bar Association of the District of Columbia under Supreme Court Rule 37.2(a). Petitioner and Respondents have filed their blanket consent to the filing of *amicus curiae* briefs with the Court on February 28, 2018 and March 19, 2018, respectively. Counsel of record for all parties have received notice of the BADC's intent to file an *amicus curiae* brief at least 10 days prior to the due date for the *amicus curiae* brief. No counsel from either party authored any part of this brief. Only *amicus curiae* made a monetary contribution to the preparation and submission of this brief.

patentees who hold patents granted since the AIA has been in effect. It will also continue to cast a cloud of uncertainty over a countless number of patents that will be issued in the future. This Court's guidance regarding the AIA's revision is of critical importance to the entire patent community.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Federal Circuit's failure to recognize the fundamental change in on-sale bar law under the AIA[2] will have the clearly unintended and damaging consequence of discouraging innovation. This incorrect interpretation of the AIA on-sale bar discriminates against and penalizes small innovators as they compete with large companies with dedicated internal facilities. Large corporations employ a vertically integrated business model with their own in-house development and distribution facilities to carry out all of the necessary work, avoiding external development contracts that linger as hidden patent validity "landmines." Since large corporations do not need to contract with third parties to manufacture or distribute their goods, they are free to conduct preparations for distribution of a future product without concern that their actions will trigger the AIA on-sale bar.

Small companies, in comparison to their vertically-integrated competitors, operate in a much different fashion and rely heavily on outsourcing development, manufacturing, and distribution activities to third

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[2] Pub. L. No. 112-29, § 3(b), 125 Stat. 284, 285-86 (2011) (codified at 35 U.S.C. § 102(a)(1)).

parties. The Federal Circuit's application of the AIA on-sale bar to transactions where an innovator contracts with a third party distributor (who agrees to and does keep the claimed invention confidential) penalizes small companies that do not have the resources or facilities to develop and distribute their products in-house. This interpretation is inconsistent with the intent of the AIA.

The issue raised by Petitioner is of utmost importance as the number of startups and small companies is growing at a rapid rate. The business model has moved away from vertical integration and shifted to outsourcing capital-intensive functions such as manufacturing and distribution. For example, small pharmaceutical and biotechnology companies and products are becoming increasingly more common. In recent years, the majority of approved drug products originated at smaller pharmaceutical companies (64% in 2016). Outsourcing allows smaller companies to be more agile, efficient, and focused. If the Federal Circuit's decision is allowed to stand and the on-sale bar of the AIA is triggered by a patentee's outsourcing of distribution functions, companies driving innovation will be penalized. And the objectives of patent law under the Constitution—"[t]o promote the progress of science and the useful arts"—will not be met. *See* U.S. Const., art. I, § 8, cl. 8. In order to protect innovation, ensure uniformity, and carry out the mandate of the U.S. Constitution, this Court should grant Helsinn Healthcare S.A.'s ("Helsinn") petition for certiorari.

REASONS FOR GRANTING THE PETITION

I. The Federal Circuit's Decision Is Inconsistent with the Statutory Text

Not only does the Federal Circuit's decision have grave implications for small companies like Helsinn, but it also violates fundamental principles of statutory interpretation. The pre-AIA on-sale bar provided, in relevant part, that a patent could not be obtained for an invention that was "on sale in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. § 102(b) (2006). In sharp contrast, the on-sale bar provision under the AIA provides, in relevant part, that a patent cannot be obtained if "the claimed invention was patented, described in a printed publication, or in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention." 35 U.S.C. § 102(a)(1) (emphasis added). The AIA added the phrase "or otherwise available to the public" to the statute. As described in Helsinn's petition, and as the PTO and AIA's sponsors have recognized, the AIA's text demonstrates that the phrase "otherwise available to the public" clarifies the scope of the preceding phrase "on sale." The AIA requires that a sale make an invention "available to the public."

The Federal Circuit's interpretation of the AIA on-sale bar fails to recognize that under the AIA, an offer for sale that does not make the claimed invention available to the public no longer triggers the on-sale bar. Confidential distribution arrangements relating to how an invention will be distributed in the future are not the kind of activity that make the invention available to the public. In failing to account for this

significant change in law, the Federal Circuit ignored this Court's admonition that "when Congress acts to amend a statute, [this Court] presume[s] it intends its amendment to have real and substantial effect." *Pierce Cty. v. Guillen*, 537 U.S. 129, 145 (2003) (quoting *Stone v. INS*, 514 U.S. 386, 397 (1995)). The Federal Circuit's interpretation does not give any effect to the new phrase in section 102(a)(1) ("otherwise available to the public") and therefore, it cannot be the proper construction of the statute. *Pierce*, 537 U.S. at 145 ("That reading gives the amendment no real and substantial effect and, accordingly, cannot be the proper understanding of the statute."). The "otherwise available to the public" phrase should be given its proper meaning and secret offers for sale should no longer implicate the AIA on-sale bar. The actions of Congress cannot be nullified by the Federal Circuit's decision here.

II. The Federal Circuit's Decision Will Have a Chilling Effect on Innovation

A. Small Innovators Are Important Contributors to Today's Economy

The patent laws need to protect the interests of inventors and create incentives for filing new patent applications in order to drive innovation. The benefit to the economy is not the only advantage that arises from protecting innovation: in exchange for a limited period of exclusivity, the public receives the benefit of the invention. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) ("[a]s we have often explained . . . the patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure

of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.").

In today's economy, the corporate structure is rapidly changing. The number of startups and small pharmaceutical and biotechnology companies has greatly increased and these agile companies are making important advances in science and technology. For example, small pharmaceutical companies acquire drugs from other companies (like Helsinn did here) or academia and seek to commercialize them. *See, e.g.*, Pet. App. 79a. These companies, like Helsinn, do not typically have their own formulation research and development laboratories and rely on third parties, such as contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") to accomplish their goals. *Id.* In contrast, large pharmaceutical companies are typically vertically integrated, which means that they carry out all of their work in-house. This work includes drug discovery, preclinical research, clinical development, regulatory work, manufacturing, distribution, sales, and marketing.

The small pharmaceutical and biotechnology sectors have experienced growth over the years. A recent study found that the majority of drugs approved by the U.S. Food and Drug Administration ("FDA") (64% in 2016) were developed at smaller pharmaceutical companies. Jennifer Alsever, *Big Pharma Innovation in Small Places*, FORTUNE (May 13, 2016), http://fortune.com/2016/05/13/big-pharma-biotech-startups/; *see also* J.A. DiMasi et al., *Innovation in Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECONOMICS, 20, 31 (2016) (noting the

growth of the small pharmaceutical sector). The biotechnology sector grew at a compounded annual rate of 3.7 percent between 2010 and 2016, from approximately $263 billion to a projected $293 billion. *2017 Global Life Sciences Outlook: Thriving in Today's Uncertain Market*, Deloitte, 2017. These statistics prove that small pharmaceutical and biotechnology companies are important contributors to driving innovation. As they continue to grow, the Federal Circuit's decision will continue to have the damaging consequence of discouraging innovation.

B. Concerns Regarding the AIA On-Sale Bar May Prevent Important Pharmaceutical and Biotechnology Products from Reaching the Market

1. Helsinn's Important Aloxi® Drug Product

Helsinn is a small, family-owned pharmaceutical company based in Switzerland. Pet. 8. The patent at issue here (U.S. Patent No. 8,598,219) protects Helsinn's drug product Aloxi®, which helps improve the lives of cancer patients by reducing nausea and vomiting caused by chemotherapy treatment.[3] Pet. 9-10. Bringing Aloxi® to the market was a very long and expensive process. At one point, the large pharmaceutical company (Roche) that Helsinn purchased the molecule from deemed the project too risky to pursue. Pet. 30-31. Helsinn took a risk and invested significant resources into developing the drug

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[3] Aloxi® is a pharmaceutical composition containing palonosetron hydrochloride as the active ingredient. Pet. 9.

product that is now Aloxi®. Pet. 30-31; Pet. App. 114a. The drug development process was not easy and Helsinn faced difficult challenges, such as developing a product that was stable enough that it did not degrade before it was finally given to patients suffering from the effects of chemotherapy. Pet. App. 95a-96a. Helsinn's persistence paid off and scientists found that lower concentrations of the active pharmaceutical ingredient promoted stability while still delivering a dose that was effective in combatting nausea and vomiting.

2. The Transaction at Issue Here

Helsinn, a family-owned company, did not have its own manufacturing or distribution facilities at the time it was developing its palonosetron product. *See* Pet. App. 34a, 79a. Around 1998, right before Helsinn began developing the product at issue, it had about 200-250 employees. Pet. App. 78a. Like many small companies that are not vertically integrated, it needed to outsource these capital-intensive activities to third parties. During the long and difficult drug development process, Helsinn needed to find a partner to share some of the risk it faced in developing the product. After an extensive search, it found MGI Pharma ("MGI"), a small Minnesota company. Pet. 9.

Helsinn entered into a license agreement and a distribution arrangement with MGI. *Id.* The agreements obligated MGI to make upfront payments to Helsinn if Helsinn's products received FDA approval. The distribution arrangement provided for MGI to purchase palonosetron products from Helsinn, if the products received FDA approval. *Id.* The agreements required MGI to keep proprietary knowledge relating

to the products confidential. *Id.* MGI adhered to its confidentiality obligations and in its SEC filings, redacted any information relating to the palonosetron formulations. *Id.* at 10. The details regarding the formulations were also omitted from a joint press release announced by both parties. *Id.* Information regarding the claimed invention was, therefore, not available to the public.

3. Distribution Arrangements Are Pre-Commercial Activity that Does not Trigger the On-Sale Bar of the AIA

Distribution agreements constitute pre-commercial planning activities and should not trigger the on-sale bar of the AIA. They merely set up a framework for distribution of a product if and when it is approved. They do not make the invention available to the public. Here, Helsinn had not obtained FDA approval for its product at the time it entered into the agreement with MGI. Moreover, there was no guarantee that the FDA would approve Aloxi® at the time of contracting. Since Helsinn did not have its own in-house manufacturing and distribution facilities, it had to outsource these functions to third parties. It needed a plan in place so that it would have the resources to bring the drug to hospitals and patients in the future, if it did receive FDA approval. Neither Helsinn nor MGI could have sold the product to anyone because the FDA had not issued its approval at the time the parties entered into the agreement. The transaction at issue in Helsinn constituted pre-commercial activity that was done to prepare for later commercialization of the product (after it was approved by the FDA). *See In re Kollar*, 286 F.3d 1326, 1334 (Fed. Cir. 2002) (holding that

"[t]he pre-commercialization process aimed at making the invention commercial" does not implicate the on-sale bar).

Judge O'Malley acknowledged that "[i]t is fair to question whether * * * distribution agreements *should* fall within the scope of the on-sale bar . . . ." Pet. App. 15a (O'Malley, J., concurring in the denial of panel rehearing) (emphasis in original). She described that the purpose of entering into distribution agreements is to "mak[e] preparations to sell products to the public in the *future*" and noted that "these agreements do not themselves effectuate consummated sales to end users." *Id.* (emphasis in original). Concerns regarding application of the on-sale bar based on the patentee's preparation and planning activities predate the AIA:

> The on-sale bar's applicability to commercial agreements entered into for the purpose of preparing to make future sales has provoked criticism long before Helsinn. *Cf. McCreery Eng'g Co. v. Mass. Fan Co.*, 195 F. 498, 502 (1st Cir. 1912) (noting that "there is reason to doubt whether an offer to deliver an article at a future time is in substance a putting on sale before the time of actual delivery").

Pet. App. 16a. Judge Reyna voiced concerns for small companies that need to outsource in his dissent in *Hamilton Beach Brands*, which arose under the pre-AIA on-sale bar: "My greatest concerns involve the implications this case will have for future innovators, most notably small enterprises and individual inventors who lack in-house prototyping and fabricating capabilities." *Hamilton Beach Brands, Inc.*

v. Sunbeam Prods., 726 F.3d 1370, 1381 (Fed. Cir. 2013) (Reyna, J., dissenting).

If small pharmaceutical and biotechnology companies face the risk that their contractual distribution agreements with third parties may years later trigger the AIA on-sale bar, it could prevent them from bringing new products to the public. Many drugs—including Aloxi®—are discovered by small pharmaceutical companies. Small companies frequently need the assistance of third parties to develop and distribute their products. Furthermore, many small companies, such as Helsinn, need to work with a third party to obtain funding to develop their products or face the risk of running out of money to complete the project. As Judge O'Malley recognized: "there is often a need to make distribution agreements public to induce investors to supply funding for product development." Pet. App. 15a. Moreover, small pharmaceutical and biotechnology companies may not be able to recoup their research and development investment if prior distribution arrangements are later found to invalidate patents that cover important products. The mounting expenses could cause these small companies to face dissolution or bankruptcy.

As the number of small innovator companies grows, their ability to work with third parties without fear of running afoul of the on-sale bar becomes increasingly important. If the scope of the AIA on-sale bar is not clear, small companies may not invest in risky projects that could provide life changing or life saving products. In order to promote innovation and protect the interests of all inventors (including small ones), this

Court should grant Helsinn's petition for a writ for certiorari.

III. The Federal Circuit's Decision Results in the Inconsistent Application of the AIA On-Sale Bar

While a vertically integrated corporation can make preparations for development and distribution of a product in-house without concern that these activities would invoke the AIA's on-sale bar, a small company (such as Helsinn) cannot. The different results—from application of the same statute—cannot be reconciled.

A. Small Corporations Without In-House Distribution Facilities Will Be Disadvantaged if This Court Does Not Intercede

With the business structure shifting away from vertical integration (*see supra*), outsourcing will become a mandatory part of doing business. In order to survive and compete, small companies will need to rely heavily on a number of third party providers. CROs and CMOs will help them with their research and development projects. They will also need third party distributors and outside investors. By simply contracting with a distributor prior to the critical date, a patentee could trigger the AIA on-sale bar and years later lose the patent protecting its valuable invention.

Large corporations, however, do not have to hire third parties to help with development and distribution. They have these resources in-house and can rely on their own warehouses and distribution channels throughout the country. Vertically integrated companies do not need to contract with distributors

and therefore do not typically engage in activities resulting in an offer for sale of the claimed invention.

The Federal Circuit's decision penalizes small pharmaceutical companies for outsourcing and places them in the difficult position of losing their patent rights or creating their own in-house distribution facilities. Doing so would greatly increase costs and divert economic resources away from developing important new drug products. Amy V. Beekman and Richard B. Robinson, *Supplier Partnerships and the Small, High-Growth Firm: Selecting for Success*, 42(1) J. SMALL BUSINESS MANAGEMENT, 59, 72 (2004) ("longer-term [supplier] relationships offer significant benefits and [] these benefits are enduring . . . In the sample, 86 percent of the 91 [pharmaceutical] firms had sales that grew 15 percent or greater every year during a three-year period . . . ."). Furthermore, the costs to bring new drugs to market are approximately $2.6-2.8 billion dollars. J.A. DiMasi, 47 J. HEALTH ECONOMICS at 31 (the cost is approximately $2.8 billion when estimated R&D costs incurred after initial approval are added); Jerry Avorn, *The $2.6 Billion Pill—Methodologic and Policy Considerations*, 372(20) NEW ENG. J. MED. 1877, 1877 (2015). Since these costs do not vary significantly between large and small pharmaceutical companies, saving costs becomes of great importance to the small innovators. *See* DiMasi, 47 J. HEALTH ECONOMICS at 29.

To ensure that a contractual relationship with a third-party distributer would not trigger the on-sale bar of the AIA, small companies would have to file patent applications within one year of entering such an agreement. While at first glance this does not seem too

difficult, it ignores the impracticality, expense, and burden this would place on small innovators. First, patent applications for all projects—whether or not they are successful—will have to be filed. Potential new products fail to reach the market for a number of reasons, including lack of commercial viability and failure to achieve the desired results.

Second, requiring small companies to file patent applications on all proposed inventions could cost a great deal of money. Justice Breyer noted in *Halo Electronics v. Pulse Electronics* that costs like these can prevent an innovator from getting a small business up and running. *See infra*. Moreover, this added burden is inconsistent with the business model of small companies as they strive to reduce costs and operate efficiently. Filing patent applications on projects that do not even end up being successful will waste the precious resources of small businesses. Drug products, like Aloxi®, that improve the quality of life of cancer patients, may not be able to make it to the market. The general public will be harmed and will miss out on important products that not only save lives, but improve the quality of life, often on a daily basis.

B. This Court Should Construe the AIA On-Sale Bar to Maintain a Consistent and Uniform Application

The on-sale bar of the AIA should be construed in a way that ensures a uniform application. Small companies should not be penalized and face additional burdens that do not affect vertically integrated companies. In a recent patent case, this Court considered the harm to small innovators in construing Section 284 of the Patent Act. *Halo Elecs., Inc. v. Pulse*

Elecs., Inc., 136 S. Ct. 1923 (2016). In *Halo Electronics*, Justice Breyer agreed with the majority and filed a concurring opinion to express his understanding of the limits imposed on Section 284 that "help produce uniformity in its application and maintain its consistency with the basic objectives of patent law." *Id.* at 1936. Justice Breyer considered the interests of small businesses and innovators in agreeing with the majority's interpretation of Section 284:

> The Court does not weaken this rule through its interpretation of §284. Nor should it. It may well be expensive to obtain an opinion of counsel. See Brief for Public Knowledge et al. as Amici Curiae 9 ("[O]pinion[s] [of counsel] could easily cost up to $100,000 per patent"); Brief for Internet Companies as Amici Curiae 13 (such opinions cost "tens of thousands of dollars"). *Such costs can prevent an innovator from getting a small business up and running.*

Id. (emphasis added). Justice Breyer recognized the harm that could result from requiring small businesses to obtain an opinion of counsel. The resources and expense required to do so could discourage innovation and prevent a small business from getting off the ground. The harm would occur absent this Court's intervention. Inconsistent application of the AIA's on-sale bar could discourage lawful innovation and place additional monetary burdens on small innovators who are trying to get small companies up and running.

* * *

The on-sale bar of the AIA should be construed in a way that produces uniformity in its application and avoids inconsistent results. This Court should grant certiorari here to prevent the Federal Circuit's misinterpretation of the AIA from discouraging innovation and preventing important innovations from reaching the market.

CONCLUSION

For the foregoing reasons, amicus curiae urges the Court to grant Helsinn's petition for a writ of certiorari.

Respectfully submitted,

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No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC. AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) AS *AMICUS CURIAE* IN SUPPORT OF PETITION

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Biotechnology Innovation Organization ("BIO") is the principal trade association representing the biotechnology industry. BIO has more than 1,000 members, which span the for-profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or mid-size enterprises that have annual revenues of under $25 million, and that count their patents among their most valuable business assets. Because modern biotechnological products commonly involve lengthy, resource and investment-intensive development periods, BIO's members depend heavily on robust patent rights and a fair system for adjudicating their validity. Accordingly, certainty regarding the types of transactions and what must be publicly disclosed about those transactions to qualify as invalidating activities under the on-sale bar of the America Invents Act (AIA) is of great importance to BIO.[1]

INTRODUCTORY STATEMENT

Small biotechnology companies are responsible for 70% of the global clinical pipeline and 84% of all drug

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1. BIO has no stake in the result of this appeal. Pursuant to Supreme Court Rule 37, all parties have consented to the filing of this brief. All parties were given notice of *Amicus'* intent to file this brief at least 10 days prior to its due date. No party other than the *amicus curiae*, its members, or its counsel, have authored the brief in whole or in part or made any monetary contribution intended to fund its preparation or submission.

development programs for rare diseases.[2] Imagine a typical example of one of the more than 2,000 small biotech companies in the United States. It was founded as a university spinoff to develop a treatment for one of the 7,000 rare diseases that affect one out of five Americans – on an idea that, at the time, was deemed too speculative by larger, established biopharmaceutical companies. The small company likely has fewer than 50 employees, occupies a leased facility, is burning upwards of $10 million per year, and has access to only enough venture capital to finance another fifteen months of research. The board is eager to put the business on more sustainable footing.

While initial research results are promising, everyone knows that it takes on average more than ten years of additional R&D before a new biotech therapy can be approved by the U.S. Food and Drug Administration.[3] But chances of that happening are slim: the likelihood that any of the company's new medicinal molecules will even advance to human testing is less than 1:1000. And the few compounds that do enter human testing empirically have a close to 90% failure rate.[4] What's more, the company has neither the funds (the out-of pocket costs of

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2. David Thomas and Chad Vessel, *Emerging Therapeutic Company Investment and Deal Trends, BIO Industry Analysis 2017*, available at: https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%202007-2016.pdf

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4. *Id.*

commercializing a biotech drug exceed $1.3 billion[5]) nor the expertise to conduct human clinical testing (this being the domain of larger biopharmaceutical companies). The company needs a partner to assume such cost and share the risk.

The company's leaders are eager to enter into discussions with potential partners and investors. Its research program includes valuable trade secrets, including samples and descriptions of several thousand new medicinal molecules. There is great concern about what can be disclosed in partnering meetings. Potential partners and investors want sufficient details about the company's research but are reluctant to sign confidentiality and non-disclosure agreements too soon.

Moreover, the small company does not yet know which of its thousands of experimental molecules will be the best candidates for human testing and should therefore be patented. Proactively filing hundreds of patent applications would be wasteful and unrealistic.[6] The company plans to file patent applications only for those molecules that are selected for human testing – but

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5. Joseph A. DiMasi, Henry G. Grabowski, Ronald W. Hansen, Innovation in the pharmaceutical industry: New estimates of R&D costs, *Journal of Health Economics*, Volume 47 May 2016, pp. 20-33.

6. Indiscriminate pre-emptive patent filing would tend to suppress pre-patent exploration of an invention to avoid potential "public" disclosure, thus stifling innovation and creating burdens on the patent system. *See* Christopher A. Cotropia, ***The Folly of Early Filing in Patent Law***, 61 Hastings L.J. 65 (2009); D. Karshtedt, ***The Riddle of Secret Public Use: A Response to Professor Lemley***, 93 Tex. L. Rev 159 (2015).

in order to get to that point, a partner is first needed. Fortunately, there are potential partners, but the ones willing to offer the most favorable terms are not interested in licensing but instead propose to acquire the program with a license of co-development rights back to the small company. Other potential partners are willing to make a preliminary investment but demand contingent assignment rights under which they would get to own the program for a predetermined payment if certain future milestones are met. The company's CEO and board are pleased: they deem such terms reasonable and a win-win for both sides.

Unfortunately, the company's lawyers are highly concerned because of a recent decision in the Court of Appeals for the Federal Circuit. *Helsinn v. Teva*, they explain, could well cause the proposed transaction to ruin future chances of patent protection for the company's molecules, and thereby destroy the value of the research program entirely. And the proposed deals would be deemed to place the company's secret molecules in the public domain, even though none of these molecules would actually be disclosed to anyone but the prospective business partner. Ultimately, the company decides to forego the proposed favorable deal and suspends its research program in the hope of finding other funding in the future. For the time being, research is not being done, and patients living with a rare disease will defer their hopes for a new treatment option.

Under the lower court's decision, no such problem or delay would be experienced if the inventors instead worked at a large pharmaceutical company that has the resources to develop its products without seeking partners. The

decision below, if allowed to stand, will impact innovative businesses of all sizes, but it will impact smaller companies more directly, and more harshly. Smaller companies are more dependent on partnering and external funding, and are more likely to have to report business transactions publicly, which would greatly increase the risk of unfairly triggering a patent-defeating event. The result below is especially harsh when a "sale" is deemed to have occurred in a clearly pre-commercial setting, long before it is even clear whether a biotech invention can receive FDA approval and actually be sold to the public, and where the transaction was undertaken to fund the development of the invention.

SUMMARY OF THE ARGUMENT

The Court should grant the writ for at least four reasons. First, it involves an important question of statutory construction suitable for resolution by this Court. The Court of Appeals declined to construe the 2011 amendments to 35 U.S.C. § 102(a), to address the effects of these amendments on its prior jurisprudence, and to explain how its ruling is grounded in the existing statute, resulting in a decision that is at once tentative and ambiguous.

Specifically, the Court of Appeals failed to explain what effect should be given to the amended language requiring that "the claimed invention was ... on sale, or otherwise available to the public." By avoiding discussion of this text, and by ruling that "if the existence of the sale is public, the details of the invention need not be publicly disclosed" (Cert. Pet. App. 43a), the Federal Circuit creates not only unmanageable uncertainty about the validity of

patents, but also an unnatural reading of section 102(a), which requires the claimed invention, not the sale, to be available to the public. The resulting business uncertainty is compounded by the lower court's unsuccessful effort at framing a narrow fact-bound ruling, which recites a haze of factors whose relevance to the on-sale bar would have been unclear even before the America Invents Act (AIA), Public Law 112-29-Sept. 16, 2011 amendments. Guidance from this Court would greatly assist the Court of Appeals in its task of construing the statute, thereby alleviating the uncertainty currently experienced by patent applicants and patent owners.

Second, the decision below is inconsistent with the United States Patent and Trademark Office's (USPTO) current patent examination practices. Since 2013, more than 300,000 patents have been examined and issued by the USPTO under an interpretation of the AIA that is now in doubt. Patent owners today are investing and building businesses in reliance on such patents. Yet, other than expressing disbelief that Congress might have wanted to modify its preexisting on-sale jurisprudence, the Court of Appeals offered no explanation why the USPTO's considered interpretation of the statute is unreasonable. In the interest of the integrity of the patent system this Court should intervene soon, or at least invite the views of the United States.

Third, in light of the AIA's territorial expansion of prior art, the decision below raises important questions about the effect of purely foreign conduct on the patentability of inventions made in this country. The Court of Appeals understood that its decision for the first time extends a patent-defeating effect to foreign conduct

having no nexus with, and being undetectable from, the United States, yet declined to discuss why Congress would have intended such an untenable result. This question is genuinely important for U.S. innovators who seek business partners abroad, and for foreign innovators seeking access to the U.S. market.

Fourth, no policy purpose would be served by letting the lower court opinion stand. To the contrary, the decision conflicts with Congress' stated policy goals, including substantive harmonization and creating more predictability for businesses and the public. By preserving a particularly problematic category of secret prior art in the amended 35 U.S.C. § 102, patents would be denied to deserving inventors who could not have known of invalidating business transactions, with no attendant benefits to the public. This would be compounded by expanding the scope of such secret prior art to the rest of the world. To the extent the Court of Appeals may have been concerned about secret commercial exploitation of later-patented inventions, it is worth noting that Congress, in the AIA amendments to 35 U.S.C. § 273, plainly endorsed the possibility that inventions can be secretly commercialized for profit and competitive advantage without creating prior art and without defeating the patentability of later-filed patent applications. The lower court's decision will be particularly detrimental to biotechnological innovation, where a majority of the new product development pipeline is held by small companies that depend on development and investment partnerships.

ARGUMENT

I. The Court Should Provide Guidance on the Statutory Construction of the 2011 Amendments to 35 U.S.C. § 102(a).

This Court should intervene to provide an answer to the dispositive question in this case: does a commercial transaction that does not inform the public about the claimed invention, nor make the invention available to the public, constitute prior art under the 2011 amendments to 35 U.S.C. § 102? There is no reason to let this urgent question fester for future resolution. The question is not narrowly fact-bound, and will not be presented any differently in the next case.

(a) The Court of Appeals' Atextual Interpretation of the AIA Sends Conflicting Messages.

The Court of Appeals declined to engage in any statutory construction of the 2011 amendments to 35 U.S.C. § 102, even though statutory construction was central to the district court holding and necessary to the disposition of the case. The amendments to 35 U.S.C. § 102 are significant, substantive, and generated more legislative commentary than any other section of the AIA. *See* J. Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J., 435, at 449 (2012). In such a case, statutory construction is necessary.

However, while the Court of Appeals declined to say that the AIA modifies any aspect of its caselaw, it balked at saying that it does not. On the one hand, the panel's

analysis seems to contain an implicit acknowledgement that the AIA might incorporate a public disclosure requirement that might modify the lower court's on-sale caselaw in some unstated way, as shown by the panel's repeated emphasis on the content of public press releases, MGI's 8-K, and previously available public information. Cert. Pet. App. 38a-39a. The panel's holding that "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed" (Cert. Pet. App. 43a) indicates the same. Notably, *before the AIA*, public knowledge of the existence of a sale was not relevant to whether a commercial sale had prior art effect or not. *See, e.g., In Re Caveney*, 761 F.2d 671, 675 (Fed. Cir. 1985); *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001).

While the lower court's reasoning thus suggests that under the AIA a completely undisclosed business transaction would not operate as patent-defeating prior art, this is not necessarily so. The Court of Appeals unhelpfully warns that even entirely secret commercial sales may have prior art effect under its caselaw in the future, just as would have been the case before the AIA. Cert. Pet. App. 35a fn 7. Businesses, inventors, and the public are thus left at a loss.

Judge O'Malley's opinion concurring from denial of *en banc* rehearing does little to clarify the uncertainty caused by the panel's hedging. Judge O'Malley writes:

> [We did] not suggest that publicly announced agreements will always trigger the on-sale bar, nor [did we] suggest that secret sales never will. As we explained in *Medicines*, the confidential

> nature of a transaction is just one of several factors for determining whether the transaction rises to the level of a commercial sale such that the on-sale bar would apply.

Cert. Pet. App. 4a-5a. Judge O'Malley's statement, while correct, distracts from the main issue of this case. The real question is not how to determine when a transaction rises to the level of a commercial sale. The critical question is how to determine when a commercial sale rises to the level of prior art. This, the Federal Circuit declined to answer.

(b) The Court of Appeals' Concerns Over Abrogation of its On-Sale Jurisprudence are Overstated.

The change in the Federal Circuit's on-sale jurisprudence that would be caused by petitioner's interpretation of 35 USC § 102(a) is unlikely to be as fundamental or sweeping as the lower court believes. The Federal Circuit has developed comprehensive guidance on whether a transaction qualifies as a commercial sale or offer for sale, often involving fact-intensive questions of offer, acceptance, and contract formation; of delivery and payment terms; and whether the object of such a sale was sufficiently developed to qualify as a complete invention, ready for patenting. This body of caselaw continues to be applicable because the new section 102(a) still requires courts to engage in all the same inquiries: a transaction will still need to qualify as a commercial sale, the date of the sale will still need to be determined, and the invention will still need to be found ready for patenting. Only once these elements are established would courts additionally ask: "and did this commercial sale make the invention available to the public?"

Thus, the meaning courts have given to the words "on sale" for over a century remains undisturbed by the AIA. Likewise, nothing in the AIA abrogates this Court's seminal guidance in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), establishing the two principal conditions that an invention be the subject of a commercial offer for sale, and that it need not be reduced to practice so long as it is ready for patenting. Properly viewed, the 2011 amendments to 35 U.S.C. § 102 merely add a third condition, public availability, without displacing the other two.

(c) Judge O'Malley's Proposed Statutory Construction Has No Bearing on the Scope of "On-Sale" Prior Art After the AIA.

The only textual analysis of the 2011 amendments to 35 U.S.C. § 102 in the court below is found in Judge O'Malley's concurrence from denial of *en banc* rehearing,[7] in which Judge O'Malley explains that the words "otherwise available to the public" in section 102(a)(1) do not modify the preceding clauses.[8] Cert. Pet. App. 9a. For support, Judge O'Malley points to the provisions at 102(b)(1)(B), which juxtapose the terms "disclosure" and

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7. No trace of Judge O'Malley's analysis was contained in the precedential panel opinion, and it is unknown whether the other panel members share her reasoning.

8. If that were the case, the "public use" requirement would be equally unmodified, thus laying the foundation for preserving the patent-defeating effect not just of secret sales, but also of non-disclosing "public uses" that do not make the invention available or known to the public, such as in *Egbert v. Lippman*, 104 U.S. 333 (1881).

"publicly disclosed," thereby suggesting that not all prior art disclosures are necessarily "public." *Id.* 10a-11a.

This interpretation reads too much into section 102(b)(1)(B). The relevant section provides:

> (b) Exceptions.—
>
> (1) [...] A disclosure made 1 year or less before the effective filing date of a claimed invention **shall not be prior art to the claimed invention under subsection (a)(1)** if— [...]
>
> (B) the subject matter disclosed had, **before such disclosure, been publicly disclosed** by the inventor [...].

(Emphasis added).

Congress amended section 102(b) to specify what kind of event would not constitute patent-defeating prior art if it occurred within one year before the invention's effective filing date, referred to as the "grace period." Section 102(b)(1)(B) does not answer one way or another whether prior art under the AIA must be publicly available or not. Instead, a reading of subsections 102(a)(1) and (b)(1) together reasonably stands only for the simple proposition that all prior art events are disclosures, but not all disclosures are prior art.

Section 102(b)(1) specifies that not all third-party "disclosures" matter for purposes of the grace period – disclosures of the invention are relevant only if they would constitute an instance of patenting, printed publication, public use, on sale, or otherwise being made available to the public (i.e. "prior art ... under subsection (a)(1)").

Indeed, Congress's use of different words, "disclosure" and "prior art," suggests that the two are not coextensive.[9] Thus, other disclosures that do not constitute "prior art ... under subsection (a)(1)" would be irrelevant. An example would be the mere sharing of the details of an invention between business partners who are under an obligation of confidentiality.

Section 102(b)(1)(B) then permits the patent applicant to disqualify those disclosures that would constitute prior art under subsection (a)(1) and that were made one year or less before the effective filing date. In order to do so, the applicant must have antedated the disclosure with her own earlier disclosure. But again, not any applicant disclosure will work – only one that was made "publicly" will suffice.

By adding the word "publicly," Congress ensured that the applicant's antedating disclosure would *itself* have prior art effect, as it must. This is because section 102(b)(1)(B) does not limit when the applicant's public disclosure must have been made relative to the claimed invention's effective filing date. Thus, by its plain terms, section 102(b)(1)(B) allows a patent applicant to rely on her own public disclosures dating to *more* than 1 year before

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9. *See also* 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Leahy)("Indeed. . . subsection 102(b)(1)(A), as written, was deliberately couched in broader terms than subsection 102(a)(1). This means that any disclosure by the inventor whatsoever, whether or not in a form that resulted in the disclosure being available to the public, is wholly disregarded as prior art."); (statement of Senator Hatch)("Indeed, a disclosure that does not satisfy the requirements to be prior art under section 102(a), nonetheless constitutes a disclosure that is fully protected under the more inclusive language of section 102(b).").

the effective filing date. For example, an applicant could properly disqualify a printed publication of the claimed invention made one year or less before the effective filing date with a public disclosure made five years before the effective filing date. The addition of the word "publicly" was thus necessary to avoid untenable results: absent a strict requirement for "public" disclosure, an applicant could secretly disclose her invention in ways that do not constitute prior art, wait indefinitely until someone else discloses the invention in a form that *does* constitute prior art, and then wait another whole year before filing a patent application.

Thus, Congress's choice of the terms "disclosure" and "publicly disclosed" in 102(b)(1)(B) can more simply and reasonably be explained as an effort to ensure that the AIA's grace period and prior art provisions work together harmoniously without producing aberrant results.

II. The Federal Circuit's Holding Is Inconsistent with the Government's Statutory Interpretation, Casting Doubt on Thousands of Patents.

(a) Patents Examined and Issued by the USPTO After the AIA May be Susceptible to Validity Challenges Based on Secret Prior Art.

The USPTO has interpreted post-AIA section 102(a) consistent with Helsinn and numerous *amici*, including BIO. Accordingly, for AIA patent applications, the USPTO has instructed its examiners to disregard secret sale activity as prior art. *United States Patent Office Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith*

America Invents Act, 78 Fed. Reg. 11,059,11,062; *see also* United States Patent Office Manual of Patent Examining Procedure § 2152.02(d) (9th ed. 2015). The USPTO started examining patent applications under the new prior art provisions on March 16, 2013. It is estimated that more than 300,000 patents have been examined and granted under the AIA's first-inventor to file provisions.

Clarification as to the proper statutory construction by this Court is urgent for these patentees who must consider the potential infirmities of patents issued under the USPTO's interpretation. Patents must continue to be examined, and patentees must continue to invest and build businesses in reliance on such patents. Meanwhile, available steps to potentially cure issued patents of problems arising from these divergent understandings of current section 102(a), such as reissue, 35 U.S.C. § 251, and supplemental examination, 35 U.S.C. § 257, are of little help. There are downsides to using these procedures: time and expense would be required to educate a new examiner on the claimed invention, and the patent may never successfully reemerge from reissue or supplemental examination. Reissue, for example, will only be granted if the patentee concedes an "error" that may have rendered the patent "inoperative or invalid." 35 U.S.C. § 251(a). No patentee would undertake such steps lightly. Thus, a reasonable business would be ill-advised to incur expense and risk without certainty as to what the new section 102(a) in fact means.

(b) Guidance is Needed So that Innovators Can Pursue Patenting, Commercial Transactions, and Business Activities Without Fear of Inadvertently Losing Their Rights.

Clarification is also necessary for inventors currently prosecuting patent applications and businesses structuring their transactions. While the USPTO's examination guidelines are consistent with the statutory text, the Federal Circuit's decision has cast them into doubt, leading to potentially inadequate patent examination that fails to protect inventors and the public. The Federal Circuit's ambiguity about the existence of a public availability requirement leaves many unanswered questions. For example, one or more arms' length transactions may precede the introduction of a product in the market. Sometimes such transactions are kept entirely secret – which, as the Federal Circuit unhelpfully cautions, may or may not save them from becoming prior art. More often, these transactions are referred to one way or another in the public sphere, for example by press release or SEC filing. Without knowing how to judge whether these references constitute prior art under section 102(a), businesses will not know how to govern reporting of their business activities, and patent applicants will not know what information to report to the USPTO during patent prosecution.

This issue is further complicated when one considers the effect of the Federal Circuit's holding on other portions of the section 102(a). The panel concluded that Congress' addition of "or otherwise available to the public" did not mean that prior art had to reveal an invention to the public to be invalidating. If the "public availability" clause

of section 102(a) indeed does not modify the preceding clauses, this would necessarily mean that "public use" references also do not need to make an invention available to the public to be prior art. If this is the case, businesses need to know. Transactions and public mentions of commercial activity are difficult to structure under the current state of the on-sale bar, but it is even more difficult to adjust the manner in which one "uses" an invention internally in one's business to avoid the pitfalls of the panel opinion. Thus, innovators who are using processes or products in secret may need to immediately file for patent protection, if still available.

(c) The Legislative History Supports the USPTO's Statutory Interpretation.

The arguments for or against the USPTO's interpretation of section 102(a) need not be repeated here, nor is it necessary to reprise the AIA's legislative history. But it would be fair to state that the USPTO's interpretation is supported by the legislative history, whereas the Federal Circuit's conclusion is not. Congress clearly removed all territorial restrictions on prior art from section 102(a), meaning that prior art references arising anywhere in the world can invalidate patents. Only two rationales are relevant to the "otherwise available to the public" inquiry: (i) Congress meant to make prior art global, but publicly accessible, or (ii) Congress meant to preserve secret prior art, but make it global. The legislative history includes support for only one interpretation. This is not an instance of competing legislator narratives and contradictory Congressional statements. Both the House and Senate Reports, for example, state plainly that Congress intended prior art under section 102(a) to

be art that is "available to the public." *See* H.R. Rep. No. 112-98, at 42, 43 (2011); S. Rep. No. 110-259, at 9, 32 (2008).

III. The Lower Court's Decision May Have Extraordinary Extraterritorial Implications That Were Likely Unintended by Congress.

Patent law is territorial. Prior to the AIA, the types of prior art embodied in 35 U.S.C. § 102(a) and 35 U.S.C. § 102(b) could be grouped into two categories: (1) patents and printed publications, and (2) knowledge, use, and on-sale activities. Category (1) prior art could exist "in this or a foreign country" whereas category (2) prior art was explicitly limited to those activities occurring "in this country." Foreign sales, use, and knowledge did not qualify. Thus, for over 100 years the policy of the on-sale bar was concerned with the domestic market and the interests of the American public. In harmonizing United States patent law with international practices through the AIA, Congress removed territorial restrictions on category (2) prior art.

The Federal Circuit's decision raises important questions about the effect of purely foreign conduct on the patentability of inventions made in this country. By including within the ambit of 102(a)'s on-sale bar commercial activity that does not convey an invention to the public, the Court of Appeals' decision for the first time extends a patent-defeating effect to foreign conduct having no nexus with, and being undetectable from, the United States.

No public policy is served by this result, indicating that it was not intended by Congress. The rationale

underpinning the pre-AIA on-sale bar was to prevent products long on sale in this country from being later withdrawn from the public by delinquent patenting. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148-49 (1989). Similarly, courts were concerned that secret commercialization would permit an inventor to exploit his invention for an extended period of time before filing for patent protection, effectively extending his period of exclusivity to the detriment of the public. *See, e.g., Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829). But secret foreign sales do not implicate either of these concerns. For example, a non-public transaction between Japanese and Korean companies in Seoul, without more, does not impact what goods are available to American consumers, nor does it have any relevance to an unknowing domestic inventor's likelihood of obtaining patent protection.

Indeed, the Federal Circuit's ruling is in tension with United States patent law's focus on how a patentee orders his affairs, not the unknowable activities of third parties. This Court and the Federal Circuit have focused on the concern that the patent applicant will delay his patent filing in order to commercially profit from his invention beyond the statutory term. Cert. Pet. App. 13a (collecting cases). As expressed in *Pfaff*, the patent laws seek to protect "the inventor's right to control whether and when he may patent his invention." *Pfaff*, 525 U.S. at 65 (emphasis added). And even in other contexts, such as patent exhaustion, this Court has explained that it is the patentee's own decisions that determine when his rights will be extinguished. *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523, 1537 (2017). To be sure, foreign activities that make inventions available to the public

are relevant to United States patent law in an age of the internet, borderless social media, and international online retail sales. But there is no explanation of why our patent laws would suddenly focus on secret foreign activities that inherently cannot affect U.S. inventors and the American public.

In turn, foreign inventors are just as likely to be unjustly impacted. Prior to the AIA, sales (public and non-public) in foreign countries had no impact on an inventor's ability to obtain patent protection in the United States. Now, under the Federal Circuit's ruling, non-public transactions that may not be patent-defeating and do not even constitute a "sale" in a foreign country can be patent-defeating in the United States. For example, the Federal Circuit looks to the Uniform Commercial Code (U.C.C.) to determine whether a transaction constitutes a commercial sale or offer for sale under section 102(a). *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) (en banc). But many countries do not have an equivalent to the U.C.C. We know from the Convention on Contracts for the International Sale of Goods that a number of countries permit oral contracts for the sale of goods, whereas the U.C.C. does not, and many countries do not follow the "battle of the forms" approach embodied in the U.C.C. *See* T. McNamara, *U.N. Sale of Goods Convention: Finally Coming of Age?*, 32-Feb. Colo. Law 11 (2011). Thus, in essence, the Federal Circuit's opinion reaches into foreign domains to control the activities of foreign inventors. But there is no policy support for regulating such foreign, non-public conduct.

IV. The Negative Policy Ramifications of the Federal Circuit Decision are Contrary to the Purposes of the AIA and Make Meaningless Explicit Protections that Congress Wrote Into the Statute.

No productive policy is served by permitting the lower court decision to stand. To the contrary, the decision stands in tension with Congress' stated policy goals, including fostering harmonization with international practice[10] and creating more predictability for businesses and the public. It also operates inconsistent with the long-standing principles underlying the "on-sale bar," namely this Court's concern that patenting inventions previously on sale will remove existing knowledge from the public. *Pfaff*, 525 U.S. at 64; *Bonito Boats*, 489 U.S. at 141. Instead, the knowledge of the invention disclosed prior to filing the patent applications is not equivalent to what was "removed from public use" by an issued patent.

Rather, the Federal Circuit set up a scenario wherein by preserving a particularly problematic category of secret prior art in the amended 35 U.S.C. § 102, patents are denied to deserving, and innocent inventors who could

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10. The patent laws of significant United States trading partners do not bar patents on the basis of secret sales. For example, under European Patent Office law there is no bar for patenting after a confidential disclosure related to commercial use, e.g. a sales agreement. E.g., *Union Carbide Corp. v. Linde A.G.* [1991] T024188 [E.P.O.] Japan has a sale bar, but if the invention is offered for sale in secret, or under a duty of confidentiality, novelty is preserved. Article 29 Japan Patent Office ("JPO"). One skilled in the relevant art must be able to understand the invention as a result of the public sale. JPO Examination Guidelines Part II. Chapter 2. Section 1.5.3(3)(II).

not have known of invalidating business transactions. This is because the amended prior art provisions at 35 U.S.C. § 102(a) treat all patent applicants the same, regardless of who created such prior art. Thus, if a prior "secret sale" constitutes prior art, it does so against any patent applicant – not just against applicants that were parties to the sale, but also against applicants who independently invented, diligently disclosed their invention in a patent application, and who could not have known of that sale at all. This unfairness is compounded by expanding the scope of such secret prior art to the rest of the world. There is no competing policy support for the regime created by the Federal Circuit's system; only inscrutable complications for innovative business.

To the extent that the Federal Circuit based its decision on a policy-based concern that removing secret sales from the scope of section 102(a) prior art would incentivize such transactions to the detriment of the public, that concern is ameliorated by the fact that Congress plainly condoned such activity in the AIA itself. In 35 U.S.C. § 273, Congress explicitly provided protections for inventors who secretly commercialize their inventions for profit and competitive advantage, without creating prior art, and without defeating the patentability of later-filed patent applications.

In 35 U.S.C. § 273, the AIA established a comprehensive set of "prior commercial user" rights under which a commercial user can engage in a for-profit exploitation of an invention for more than one year before the filing date of another's patent application. A typical scenario would be a business that uses an inventive machine to more efficiently manufacture articles for sale, thus gaining a

competitive advantage over competitors, or a company that sells services to customers using its own inventive software. If the invention is later independently patented by another, and that patentee then sues the prior user for such longstanding, ongoing commercial use, the prior user has a personal defense against claims of infringement.

To establish this defense, the exploitation of the later-patented invention must precede the filing of the later patent application by more than one year and must be "commercial" and "internal." Importantly, such exploitation by the first user does not invalidate the inventor's later filed patent. 35 U.S.C. § 273(g).

Thus, Congress recognized that even significant commercial, for-profit exploitation of an invention, including the sale of manufacturing services and other benefits, does not constitute prior art, so long as it does not disclose the invention to the public. If such exploitation were prior art, there could not be a later patent, and the new defense codified at 35 U.S.C. § 273 would have been unnecessary.

CONCLUSION

The negative policy implications arising from the Federal Circuit's decision cannot be mitigated without intervention by the Court. For these reasons, BIO respectfully requests that the Petition for a Writ of Certiorari be granted.

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Date: April 2, 2018

No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF THE BOSTON PATENT LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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INTEREST OF THE BOSTON PATENT LAW ASSOCIATION

The Boston Patent Law Association ("BPLA") is a nonprofit professional association of approximately 1,000 attorneys and other professionals whose interests and practices are in the area of intellectual property law. Its members provide a variety of patent-related services, including patent prosecution, litigation, and licensing and serve a broad range of clients who rely on the patent system, such as inventors, businesses large and small, and universities and other research institutions. The BPLA therefore has an institutional interest in seeing that patent law develop in a clear, predictable, and coherent way in order to promote innovation and protect innovators.[1]

SUMMARY OF ARGUMENT

The BPLA believes that the patent system and its participants are best-served by clear and predictable patent laws. It is essential that all participants in the patent system understand both what the laws require and what the laws proscribe in order to effectively protect their own intellectual property and respect the intellectual property of others. This is especially true in context of collaboration with third-parties, whether it be joint development or contract manufacturing. Innovators

1. The BPLA has no financial interest in any party or the outcome of this case. This brief was neither authored nor paid for, in whole or in part, by any party. Petitioner has consented to the filing of this brief through a blanket consent letter filed with the Clerk's Office on March 13, 2018. Respondents have consented to the filing of this brief through a blanket consent filed on March 19, 2018.

need to know what conduct will or will not create a bar to obtaining patent protection. To that end, the BPLA believes the Court should grant certiorari in this case to make clear whether the meaning of "on sale" as used in 35 U.S.C. § 102(a) retains the same meaning that "on sale" had prior to the America Invents Act ("AIA"). Further, should the Court decide "on sale" has a different meaning under the AIA, the BPLA encourages the Court to provide a framework under which to analyze whether an invention is "on sale." While the BPLA takes no position on the ultimate resolution of these issues, it nonetheless believes resolving them now is critical for the predictability of law that is essential to a well-functioning patent system.

The BPLA believes this is the appropriate case for this Court to provide clear guidance on the scope of "on sale" prior art for two reasons. First, the Federal Circuit panel decision left undecided critical questions squarely raised in this case about the scope of "on sale" prior art under the AIA. Second, this is precisely the kind of case that is appropriate for review by the Court: it raises an important question of federal law that should, and only can, be settled by this Court. *See* Supreme Court Rule 10.

ARGUMENT

I. THE COURT SHOULD DECIDE WHETHER THE AIA CHANGED THE MEANING OF "ON SALE"

Prior to the AIA, 35 U.S.C. § 102 provided that "[a] person shall be entitled to a patent unless . . . (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or *on sale* in

this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102, *amended* by Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (emphasis added). Numerous cases interpreting the meaning of "on sale," as used in pre-AIA section 102, held that the existence of a sale of the invention need not be public for the sale to preclude patentability. *Helsinn Healthcare S.A. et al. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356, 1367 fn. 7 (Fed. Cir. 2017). The AIA amended the prior art provisions of section 102 to provide "[a] person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, or in public use, *on sale*, or otherwise available to the public before the effective filing date of the claimed invention." 35 U.S.C. § 102(a) (emphasis added).

As made clear by the fact that the parties, the U.S. Patent and Trademark Office ("PTO"), and amici in the Federal Circuit below have taken varying positions in their briefs on whether, and how, the AIA changed the meaning of "on sale," there is substantial confusion on the effect of these AIA amendments. The district court below, in an issue of first impression, concluded that the AIA did work a substantial change in the pre-AIA definition of "on-sale." The parties vigorously contested that result in briefing before the Federal Circuit. Under some of the competing interpretations, a wholly confidential sale could be prior art, as was the case before the AIA. Other interpretations, including the district court's, would require that a sale make the details of the invention "available to the public" in order to be prior art.

Despite this confusion, the Federal Circuit panel expressly declined to decide whether the AIA changed the meaning of "on sale." *See Helsinn*, 855 F.3d at 1368. Instead, the panel concluded "that, after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." *Id.* at 1371. In tailoring its holding so narrowly, the Federal Circuit panel decision provides little guidance on the scope of "on sale" prior art under the AIA. And the Federal Circuit declined to provide further guidance *en banc*. *See* Pet. App. at 2a.

Yet squarely at issue in this case is the broader question of whether the meaning of "on sale" changed under the AIA. Petitioner frames the Question Presented as the following:

> Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

Necessarily bound up with that inquiry is whether the inclusion of the phrase "or otherwise available to the public" in section 102 changed the meaning of "on sale" in any way. The Federal Circuit panel decision side-stepped this issue, cabining the decision to the facts of the case by only holding that "the AIA did not change the statutory meaning of 'on sale' *in the circumstances involved here*." *Helsinn*, 855 F.3d at 1360 (emphasis added). Further, the panel decision altogether avoids the issue of whether non-public sales constitute "on sale" prior art.

These are foundational issues in patent law. All participants in the patent system must be able to determine what constitutes prior art under the AIA. It is essential for an inventor deciding whether to file a patent application to understand what is prior art and what is not, and whether her business conduct will result in a loss of right. It is just as essential for a company determining a strategy for enforcing its patents to understand exactly what is prior art. Without this fundamental understanding, innovators cannot make reliable decisions.

Accordingly, the BPLA encourages the Court to grant certiorari and provide clear guidance on the meaning of "on sale," including, to the extent necessary, a framework for determining when an invention is "on sale" akin to the framework announced in *Pfaff*. *See Pfaff v. Wells Elecs, Inc.*, 525 U.S. 55 (1998) (holding the pre-AIA on-sale bar applies when two conditions are satisfied before the critical date: 1) the invention is subject of a commercial offer for sale and 2) the invention is ready for patenting). This Court should seize this opportunity to improve the predictability of patent law at the outset, before many district courts and patent examiners potentially reach conflicting conclusions on the effect of the AIA.

II. THIS IS THE PROPER CASE FOR REVIEW

A. This Case Presents a Statutory Interpretation Question of First Impression

"[C]ertiorari jurisdiction exists to clarify the law." *City and County of San Francisco, Calif. v. Sheehan*, 135 S. Ct. 1765, 1774 (2015). This includes the crucial function of clarifying the effects of amendments on statutes that this

Court has previously addressed. *See, e.g., TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S. Ct. 1514 (2017) (holding amendments to 28 U.S.C. § 1391 did not change the meaning of 28 U.S.C. § 1400(b) as interpreted by *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222 (1957)). And this is precisely the kind of case that presents such an opportunity. The AIA's amendments to section 102 have created confusion over the meaning of "on-sale." What was once an area of reasonably well-developed law with well-understood meaning pre-AIA is now rife with uncertainty concerning the extent to which a sale must be made public in order to constitute patent defeating "on-sale" prior art. This is an important issue of federal law that the Federal Circuit has twice chosen not to resolve, so this Court should provide guidance.

The BPLA believes the Court should seize this opportunity. Granting certiorari will provide the appropriate setting for this Court to perform a full analysis of "on sale" under the AIA and provide a clear statement on its correct interpretation. This widened inquiry is especially worthwhile here where whether the meaning of "on sale" has changed is a threshold issue. The Court's decision will either indicate that the extensive case law on this issue continues to apply (should the Court confirm that the meaning of "on sale" is unchanged) or spur lower courts to begin developing the contours of the law under the new meaning on-sale (should the Court confirm that the meaning of "on-sale" has unchanged). The Court should address this issue head on.

B. The Statute at Issue Has Multiple Plausible Interpretations

Granting certiorari is appropriate, as there are multiple, conflicting plausible interpretations of the statutory language, and the Federal Circuit panel decision leaves open which is the correct interpretation. For example, the district court below concluded that the AIA changed the meaning of "on sale" to require that the sale or offer for sale must be public. The PTO's position prior to the Federal Circuit opinion went further, stating that section 102(a) required that the sale make the invention itself public. *See* Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059, 11,075 (Feb. 14, 2013). The current petition shares this position. Finally, the Federal Circuit panel held that the AIA does not require the sale to make the invention public, but it failed to address whether the sale itself needs to be public. *See Helsinn Healthcare S.A. et al. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356, 1368-1371 (Fed. Cir. 2017).

At bottom, there is confusion over what "on sale" means after the AIA amendments. And the lack of guidance provided by the panel decision is made all the more evident by the concurrence to the Federal Circuit's denial of rehearing *en banc*, which spends thirteen pages attempting to clarify the panel's holding. *See* Pet. App. at 3a-16a. But, as it is not binding authority on any lower court, the concurrence does little to contribute consistency in interpreting this law. Given this confusion, the Court should address these competing interpretations and questions unanswered by the panel.

C. Resolution of the Underlying Questions in this Case has Broad Implications on the Patent System and Its Participants

The scope of the prior art is a foundational issue in our patent system. As such, the need for resolving the scope of "on sale" under the AIA extends far beyond this particular case and these particular parties. *Cf. City and County of San Francisco, Calif. v. Sheehan*, 135 S. Ct. 1765, 1779 (2015) (Scalia, J., concurring in part and dissenting in part) ("But it is also true that there was little chance that we would have taken this case to decide only the second, fact-bound QP.").

Leaving these issues unresolved now will materially impact all participants in the patent system. Predictability of the law is essential to a well-functioning patent system because participants adjust their behavior and investment of resources based on their understanding of the patent laws. Uncertainty regarding the most basic laws of patentability can reduce participation in the patent system.

The importance of resolving these issues, and doing so now, is most apparent as it concerns the PTO's examination of new patent applications. The PTO previously determined that the AIA did change the meaning of "on sale," concluding "[t]he phrase 'on sale' in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA 35 U.S.C. 102(b), ***except that the sale must make the invention available to the public***." *See* Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059, 11,075 (Feb.

14, 2013) (emphasis added). Thus, based on the Federal Circuit's *Helsinn* decision, the PTO has been applying an incorrect interpretation of section 102(a) for years. The PTO, and the entire patent system, benefits from examiners applying the correct definition of "on sale" prior art. Without clear guidance from this Court on the most basic boundaries of "on sale" prior art, the PTO may allow or reject applications due to a misunderstanding of the law. Whatever the correct interpretation of "on sale" is under the AIA, it is critical that the PTO be given that guidance as soon as possible.

Further, individuals and businesses are impacted by the uncertainty. This Court has recognized the importance of "providing inventors with a definite standard for determining when a patent application must be filed." *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 65 (1998). And it has acknowledged that a murky rule "undermines the interest in certainty." *See Id.* at 65-66. Without clear guidance on the scope of "on sale" prior art, innovators will be unable to determine whether a given transaction starts the clock to file the application. And whether the exceptions of 102(b) are available is frequently determinative in whether an inventor files a patent application.

Further, without clear guidance on the scope of "on sale" prior art, businesses also cannot determine how to structure inter-company agreements in a manner that avoids creating invalidating prior art. This can lead to inefficiencies as businesses either forgo beneficial collaboration with other businesses or reduce their participation in the patent system because the uncertainty reduces the value of patents. Either result ultimately hurts the patent system's ability to promote innovation.

CONCLUSION

For the foregoing reasons, this Court should grant certiorari. The BPLA respectfully encourages the Court to take this opportunity to clarify what effect, if any, the AIA had on the meaning of term "on sale," as used in 35 U.S.C. § 102(a).

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IN THE

Supreme Court of the United States

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Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF PETITIONER

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INTEREST OF AMICUS CURIAE

Amicus curiae Intellectual Property Owners Association (IPO) is an international trade association representing companies and individuals across all industries and fields of technology who own or are otherwise interested in intellectual property rights.[1] IPO's membership includes about 200 companies and over 12,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property before Congress and the United States Patent and Trademark Office (USPTO) and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.[2]

IPO's members invest tens of billions of dollars annually on research and development, employing hundreds of thousands of scientists, engineers, and others in the United States to develop, produce, and market innovative new products and services. Many of these innovations take years of research, failure, missteps,

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1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. Both parties have consented to the filing of this brief through blanket consent letters.

2. IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

and refinements to reach eureka moments, and still additional time to develop practical applications followed by potential commercialization. To bring new products and services to market, IPO's members often resort to contractual arrangements with third parties for supply and/or distribution because they lack the resources to do it all themselves. Further, in many industries in which IPO members operate, necessity dictates that plans for commercialization begin years before research and development has produced marketable products, particularly, for example, in the pharmaceutical, semiconductor, energy, aerospace, and automotive industries.

Because of the need to timely file for patents on their innovations, this case presents a question of substantial practical importance to IPO members: namely, whether in enacting the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (AIA) Congress changed the on-sale bar defense, as the trial court and USPTO have concluded—a determination with which the Federal Circuit disagreed. A further related question of importance to IPO is, in light of the proper statutory construction, how must IPO members conduct their business to protect and market their innovations without triggering an on-sale bar. IPO members, as well as the parties and indeed all IP stakeholders, need the clarity (if not the certainty) that only this Court can provide regarding proper application of the on-sale defense post-AIA.

SUMMARY OF ARGUMENT

There is a debate about whether Congress changed the "on-sale" defense to a patent infringement claim in enacting the AIA, as articulated in the parties' and amici briefing and the conflicting decisions of the trial court and Federal Circuit panel below. The debate has two aspects. First, whether the post-AIA on-sale bar excludes private sales, and second, whether a public sale requires that the claimed invention subject to the sale be made public to be invalidating.

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) held that Congress did not "change the statutory meaning of 'on sale'" by enacting the AIA, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1360 (Fed. Cir. 2017). However, the Federal Circuit decision is inconsistent with the USPTO's post-AIA examination guidelines, adopted before the AIA became effective and still followed today. *See* Manual of Patent Examining Procedure, Ninth Edition, Revision 08.2017, Last Revised January 2018 (MPEP) § 2152(d). These examination guidelines were previously the only authoritative guidance post-AIA on whether an invention was on-sale to bar patentability. Indeed, the USPTO's guidelines have governed examination of many hundreds of thousands of patent applications. More post-AIA innovations are being made, applications are being filed, and patents are being issued every day, and the validity and value of many of those patents will remain clouded until this Court settles the present on-sale bar debate. Similarly, both large and small innovators and their business partners need clarity now so they can organize their businesses and contracts to develop, commercialize,

and protect their innovations; making any necessary practice changes to comport with the law. Delay in clarifying this important issue risks laying serious traps for the wary, as well as the unwary.

Furthermore, if the Federal Circuit's construction of the post-AIA on-sale bar is correct, then its holding that the mere existence of a public sale or offer for sale that does not disclose the invention as claimed is inconsistent with that part of the Federal Circuit's *en banc* decision in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) stating that "the offer or contract for sale must unambiguously place the invention on sale, as defined by the patent's claims." *Helsinn*, 855 F.3d at 1366.

Finally, this case represents a fact pattern that will repeat until the legal debate over proper post-AIA construction of the on-sale bar is settled. A prompt resolution will enable the USPTO to examine patent applications and allow applicants to make appropriate disclosures regarding putative on-sale activities under the correct rubric. It also will enable IP stakeholders to mitigate their risks when contracting with others to bring innovations to market.

IPO supports the petition to resolve the debate, but takes no position on the merits of the question presented in this case, *i.e.*, whether post-AIA an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

ARGUMENT

I. Proper Application of the Post-AIA On-Sale Bar Is Critically Important to All Industries and Fields of Technology

This case presents an important issue of first impression: whether Congress substantively changed the on-sale bar in section 102 of the Patent Act when it enacted the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) . Congress made fundamental changes to the Patent Act by, among other things, redefining prior art under section 102. *See Helsinn*, 855 F.3d at 1368. The Federal Circuit expressly declined, however, to address how those changes, which it deemed limited to "public use" activities, affect application of the on-sale bar, *see id.* at 1368-69, a critically important issue that this Court should decide.

The Federal Circuit also rejected Helsinn's argument that the on-sale bar under the AIA does not include "secret sales." *Id.* at 1367-69. But as the arguments made below point out, secret prior art creates uncertainty and is a drag on the patent system, and there is some basis to believe that Congress wrote secret on-sale activities out of the on-sale bar by adding the language "or otherwise available to the public." *See, e.g.*, 157 Cong. Rec. 3415 (2011) (remarks of Sen. Leahy) ("[S]ubsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale . . . may be deemed patent-defeating prior art."). Thus, the Federal Circuit decision might leave secret prior art within the on-sale bar, given the decision's reluctance to address the issue, perpetuating uncertainty and confusion.

The Federal Circuit's reluctance is also at odds with this Court's precedent. In *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, "the only question [was] whether Congress changed the meaning of §1400(b) [the patent venue statute] when it amended §1391 [the general venue statute]." 137 S. Ct. 1514, 1520 (2017). Because the amended "version of §1391 does not contain any indication that Congress intended to alter the meaning of §1400(b)," the Court answered that question in the negative. *Id.*

But here there are arguably numerous indications that Congress intended to alter the meaning of both section 102 and the on-sale bar, as evidenced by its various considerations of whether to include the on-sale bar as an invalidity defense (and in what form), which the Federal Circuit decision acknowledges. *See, e.g.*, *Helsinn*, 855 F.3d at 1368; *cf.* Brief of Amicus Curiae Congressman Lamar Smith in Support of Appellees, *Helsinn*, 855 F.3d 1356 (No. 2016-1284), *and* Brief of Amicus Curiae 42 Intellectual Property Professors in Support of Appellant, *Helsinn*, 855 F.3d 1356 (No. 2016-1284) (presenting contrasting statutory construction views).

The Federal Circuit also held that confidential details of an invention as claimed need not be publicly disclosed to trigger the on-sale bar. *See Helsinn*, 855 F.3d at 1370-71. Conversely, a confidential sale should arguably avoid triggering the on-sale bar (even as amended by the AIA), consistent with the Federal Circuit's holding in its *en banc Medicines* decision, 827 F.3d at 1376 ("the confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature."). Yet Helsinn's partner, a publicly traded company, publicly disclosed its agreements with

Helsinn in redacted form in its Form 8-K filing to comply with SEC regulations. *See Helsinn*, 855 F.3d at 1361. Thus, the nature of this case's agreements and circumstances – where the claimed subject matter was kept secret – bear directly on how any innovator might contract with others to develop claimed inventions for commercialization, significant factors that warrant this Court's consideration.

II. The Federal Circuit Decision Is Inconsistent with the USPTO's Post-AIA View of the Scope of the On-Sale Bar

Before the effective date of the AIA, the USPTO adopted its interpretive guidelines, including the only authoritative interpretation of new AIA section 102 until the Federal Circuit decision. *See* MPEP § 2152.02(d). For the last five years, patent applicants and examiners have followed those guidelines in considering what information to disclose and the significance of that disclosure. More importantly, the USPTO has examined hundreds of thousands of patents based on a reading of the on-sale bar that is consistent with the district court's construction below, but inconsistent with the Federal Circuit's construction. According to statistics from the USPTO, just under a million patents were granted between 2013 (the year the AIA went into effect) and 2015. *See* USPTO Patent Technology Monitoring Team, U.S. Patent Statistics Chart, Calendar Years 1963-2015, available at https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last visited March 17, 2018). These numbers are increasing as time passes.

As discussed above, the Federal Circuit held that, notwithstanding enactment of the AIA, the on-sale bar applies to a public sale even if an invention is not disclosed in the terms of the sale. *Helsinn*, 855 F.3d at 1371. The USPTO's MPEP, however, takes a different view of the scope of the post-AIA on-sale bar. There, "[t]he phrase 'on sale' in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA 35 U.S.C. 102(b), *except that the sale must make the invention available to the public.*" MPEP § 2152.02(d) (emphasis added). The USPTO's MPEP further states that "[t]he pre-AIA 35 U.S.C. 102(b) 'on sale' provision has been interpreted as including commercial activity even if the activity is secret. . . . AIA 35 U.S.C. 102(a)(1) uses the same 'on sale' term as pre-AIA 35 U.S.C. 102(b). *The 'or otherwise available to the public' residual clause of AIA 35 U.S.C. 102(a)(1), however, indicates that AIA 35 U.S.C. 102(a)(1) does not cover secret sales or offers for sale.* For example, an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if it is among individuals having an obligation of confidentiality to the inventor." *Id.* (emphasis added).

Under the USPTO's post-AIA construction of the on-sale bar, the agreements in this case would not bar patentability or invalidate Helsinn's patent because the invention claimed was not "made available to the public," as the district court found. *See Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd.*, No. CV 11-3962 (MLC), 2016 WL 832089, at *51 (D.N.J. Mar. 3, 2016). Independent of whether any deference is due to the USPTO, the consistency of its construction with the district court's and the disagreement between that construction and the Federal Circuit's construction highlights uncertainty

that is unsettling to innovators and patent holders in all industries and fields of technology. That uncertainty is ripe for resolution by this Court.

III. The Federal Circuit Decision in This Case Is Facially Inconsistent with the Federal Circuit's *En Banc* Decision in *Medicines*

Medicines allows inventors to contract for manufacturing services without triggering the pre-AIA on-sale bar, provided their inventions (as defined by a patent's claims) are not "on sale." 827 F.3d at 1374 (application of the on-sale bar "requires that 'the invention' be 'on sale'" and "[t]he 'invention' is defined by the patent's claims.") (quoting 35 U.S.C. § 102(b)), 1377 ("[T]here must be a commercial sale or offer for sale. The statute itself says the invention must be 'on sale,' or that there must be an offer for sale of the invention. . . . The on-sale bar is triggered by actual commercial marketing of the invention, not preparation for potential or eventual marketing.").

But the Federal Circuit held that the post-AIA on-sale bar applies to all public sales, including sales that do not disclose an invention as defined by the patent's claims. *See Helsinn*, 855 F.3d at 1370 ("[A]n invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale is made public."), 1371 ("[A]fter the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale."). Thus, the Federal Circuit decision does not allow inventors the same flexibility for license agreements that must be publicly disclosed, *see supra* Argument Section I, that *Medicines* allows for manufacturing agreements.

Again setting aside whether the pre- and post-AIA on-sale bars allow inventors the same degree of flexibility, the inconsistency between the Federal Circuit panel below and the Federal Circuit's *en banc Medicines* decision alone is sufficient reason to grant Helsinn's petition. The Federal Circuit panel determined that a sale need only be public for the on-sale bar to apply, while *Medicines* held that the "claimed invention" must be the subject of any invalidating sale. This Court should clarify which decision controls for the benefit of all stakeholders.

Judge O'Malley took issue with this argument in the concurrence to the denial of the petition for *en banc* for this matter, which she characterized as a mischaracterization of *Medicines*. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, No. 2016-1284, 2016-1787, slip op. at 2 (Fed. Cir. Jan. 16, 2018) (O'Malley, J., concurring). Judge O'Malley correctly pointed out that *Medicines*' determination that the agreements at issue did not place the invention on sale was based on a number of factors, including confidentiality, not one of which was "of talismanic significance." *Medicines*, 827 F.2d at 1326. IPO agrees, but nevertheless maintains that the weighing of the factors underlying (i) whether the invention was the subject of a commercial sale and (ii) whether the claimed subject matter is made public, was treated differently and inconsistently in the Federal Circuit decision below, in *Medicines*, and in the USPTO guidelines, and warrants this Court's attention and harmonization.

Further, the policy discussion in the concurrence below misapprehends IPO's *amicus* position, which is that the Court should determine whether Congress changed the on-sale bar, not whether the consequences of applying

pre-AIA on-sale bar jurisprudence should be avoided on policy grounds. *Helsinn*, No. 2016-1284, 2016-1787, slip op. at 4-5 (O'Malley, J., concurring). Here, the policy issues bear directly on whether Congress intended to change the on-sale bar, and should be considered in resolving this important question.

In this regard, this Court has previously stated the policy underlying the on- sale bar: "The patent laws therefore seek both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 65 (1998). After considering that Congress allowed the inventor first a two year grace period, and then one year, the Court promulgated its two factor test for the on-sale bar. *Id.* at 65, 67-68. IPO submits this policy focus on "knowledge in the public domain" warrants this Court's consideration in the issues presented here.

In any event, in the concurring opinion below the discussion of statutory construction bolstering the Federal Circuit panel's conclusion that the AIA did not change the on-sale bar, *Helsinn*, No. 2016-1284, 2016-1787, slip op. at 5-10 (O'Malley, J., concurring), and the role of policy considerations underlying the on-sale doctrine, *id.* at 10-13, do not resolve the fundamental debate presented by Helsinn's petition. Rather, these discussions illuminate and help frame whether the Federal Circuit's, the USPTO's, or some other construction of the post-AIA on-sale bar is correct. Indeed, the concurrence below suggests that this issue is ripe for review by this Court. *Id.* at 13. As discussed *supra* at Summary of Argument, passing time leaves IP stakeholders increasingly at risk, and warrants clear guidance from this Court.

IV. This Case Presents a Unique Opportunity to Clarify the Application of the AIA's On-Sale Bar

There is no dispute about the terms of the agreements in this case. Indeed, the circumstances surrounding those agreements are commonplace in industries where patent holders, including IPO members, partner with others to develop and manufacture new products. Like many pharmaceutical companies, Helsinn needed a partner to develop a drug, bring it to market, and help the millions of cancer patients who suffer from chemotherapy-induced nausea and vomiting. As discussed above, however, the future of similar, equally-important partnerships is uncertain because the Federal Circuit decision does not clearly address the proper application of the AIA's on-sale bar to similar agreements. Also as discussed above, the lack of clarity is only compounded by conflict with *Medicines* and the USPTO's guidelines. Until the inconsistency is resolved, patent holders, prospective patentees, and other industry participants do not know how to arrange their affairs to allow them to continue contributing to society through innovation.

This case's facts are uncommon in that the four patents-in-suit claim priority to the same provisional application, but only one patent is governed by the AIA. *See Helsinn*, 855 F.3d at 1360 n.1. Thus, the Court has a unique opportunity to determine in the first instance whether Congress changed the "on-sale" bar defense to a patent infringement claim when it enacted the AIA. It is difficult to imagine a better case to resolve any inconsistency between the Federal Circuit decision in this case and its *en banc* decision in *Medicines*, or to clarify the application of the post-AIA on-sale bar, given the involvement of both pre- and post-AIA patents.

CONCLUSION

The Court should grant Helsinn's petition because this case presents important questions of first impression and it is necessary to clarify the construction of the post-AIA on-sale bar and resolve the Federal Circuit decision's ambiguity and facial inconsistency with the Federal Circuit's *en banc* decision in *Medicines* and the USPTO's guidelines.

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No. 17-1229

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TEVA PHARMACEUTICALS USA, INC., and
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INTEREST OF THE MASSACHUSETTS BIOTECHNOLOGY COUNCIL ("MASSBIO")

Founded in 1985, the Massachusetts Biotechnology Council ("MassBio")[1] is a nonprofit association of more than 1,000 biotechnology companies, academic institutions, disease foundations, and other organizations involved in life sciences and healthcare, principally all based or active in the Commonwealth of Massachusetts. Of the more than 600 MassBio members that are life sciences companies, more than 88% have less than 250 employees worldwide, and 74% have less than 50. These small and midsize biotechnology companies depend on strong patent rights and collaborations with other parties to maintain their ability to research, develop, and commercialize breakthrough therapies and cures, and to ensure that patients around the world have affordable access to those new treatments.

MassBio opposes policies and laws that threaten patient access, limit innovation, or hurt the Massachusetts life sciences industry's competitiveness in the global economy. Moreover, because of the already numerous challenges faced by small and midsize biotechnology companies and the heavy reliance of

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[1] MassBio has no financial interest in any party or the outcome of this case. This brief was neither authored nor paid for, in whole or in part, by any party. Counsel of record received timely notice of the intent to file the brief under Supreme Court Rule 37. Both Petitioner and Respondents have consented to the filing of this brief through blanket consent letters filed with the Clerk's Office on March 13, 2018 and March 19, 2018, respectively.

these innovators on patent protection, MassBio is particularly concerned with the uncertainty and chilling effect established by the Federal Circuit's decision below regarding the types of transactions that may trigger the "on-sale" bar. MassBio believes that its industry experience and perspective will provide useful information for the Court's consideration of the petition.

SUMMARY OF ARGUMENT

This case concerns a question of critical importance to the biotechnology and pharmaceutical industries: whether the public disclosure of the mere existence of confidential and often necessary pre-marketing activities can be used to invalidate an innovator's patent. The Petition requests that this Court clarify the scope of what activities qualify as prior art under the "on-sale bar" reflected in the amended language of § 102(a)(1) of the Leahy-Smith America Invents Act (AIA). Because of the significant uncertainty created by the Federal Circuit's decision below regarding the on-sale bar, and the exceptional importance of the issue to the biotechnology community, the Court should grant the petition for a writ of certiorari.

The Federal Circuit's decision below raises serious questions concerning the application of the on-sale bar to confidential pre-marketing activities that are often necessary to bring life-saving medicines to market. Notwithstanding statements by the panel and Judge O'Malley's later concurrence in the denial

of rehearing *en banc* characterizing the ruling as narrowly tailored to the particular agreement at issue, the decision in fact contains broad, sweeping language concerning public disclosure. The Federal Circuit's unusual analysis regarding the meaning of "on sale" has created murky waters for patentees in the post-AIA world. For example, the decision below is unclear as to whether the pre-AIA analytical framework for determining what constitutes a commercial sale for purposes of pre-AIA § 102(b) extends to the amended language of AIA § 102(a)(1). As a result, it remains uncertain whether public disclosure of the mere *existence* of a sale of an invention would qualify, on its own, as an invalidating act under the AIA.

This uncertainty is particularly harmful to the members of the biotechnology industry, many of whom are members of *Amicus*. In particular, the Federal Circuit's decision disproportionately affects small and midsize companies that depend on valid patents and pre-marketing collaborations in order to bring new drugs to market. The decision below has created a cloud of uncertainty over the risks associated with pre-marketing transactions and an overall chilling effect on innovation and collaboration in the biotechnology space. Absent clarification from this Court, the companies that research and develop the majority of new, approved drugs in the United States will be forced to either forgo their patent rights in order to fund the development of life-saving therapies or face the prospect of never making it to market at all.

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION CREATES SIGNIFICANT UNCERTAINTY CONCERNING THE SCOPE OF THE ON-SALE BAR UNDER AIA § 102(a)(1).

The decision below raises serious questions as to what activities may trigger the on-sale bar in the post-AIA world. In particular, the Federal Circuit's repeated and extensive focus on the public disclosure of the mere *existence* of a sale or offer for sale makes it unclear whether such disclosure, on its own, qualifies as an invalidating act under § 102(a)(1).

On the one hand, the Federal Circuit's decision included an analysis of several facts relating to the transaction between Helsinn and MGI. *See, e.g.*, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1361-62, 1369 (Fed. Cir. 2017). The Federal Circuit described the agreement between Helsinn and MGI as "bear[ing] all the hallmarks of a commercial contract for sale," noting in particular the structure of the agreement, the supply obligations, the methods of payment and delivery, and the applicable termination procedures in the event of unfavorable clinical trial results or a failure to obtain FDA approval. *Id.* at 1365, 1362. The court also emphasized that "[a]ll of the above information about the transaction was publicly disclosed," except for the specific price terms and the exact (claimed) 0.25 mg dosage of the product. *Id.* at 1362.

Judge O'Malley pointed to this analysis in her concurrence in support of the denial of *en banc* review

as evidence that the Federal Circuit's decision had properly considered a number of factors in deciding that the particular agreement at issue triggered the on-sale bar. *See Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, App. Nos. 2016-1284, -1787 (Fed. Cir. Jan. 16, 2018) (denying *en banc*) (O'Malley, J., concurring), slip op. at 2-3. The problem, however, is that the decision below considered these factors as part of the *pre*-AIA framework to find that the agreement constituted a commercial sale or offer for sale for purposes of *pre*-AIA § 102(b). *See Helsinn*, 855 F.3d at 1367 (discussing these facts as part of the analysis for the three pre-AIA patents at issue). When the Federal Circuit finally turned to address the on-sale bar *post*-AIA under the amended language of § 102(a)(1), however, the court appeared to create a new rule.

The parties had argued below at great length over whether the amended language of § 102(a)(1) changed the meaning of the on-sale bar. Petitioner argued that the amendment and the express legislative intent behind the amendment "was to eliminate secret sales as prior art and to require that the sale *make the claimed invention available to the public*" in order to be invalidating. Pet. at 7 (citations omitted) (emphasis added). *See also* 157 CONG. REC. S1370 (daily ed. Mar. 8, 2011) (statement of Senator Kyl) ("Moreover, the fact that the clause 'or otherwise available to the public' is set off from its preceding clauses by a comma confirms that it applies to both 'public use' and 'on sale.' . . . Thus new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated by the bill—an understanding on which the remainder of the bill is

predicated."). As such, Petitioner argued that under the AIA's amended § 102(a)(1), the on-sale bar should not apply where the claimed invention—in this case, the precise formulation of palonosetron—was not made available to the public or placed into the public domain. Respondents, on the other hand, argued below that the preservation of the term "on sale" within the language of § 102(a)(1) indicated that Congress did not change the meaning of the on-sale bar or disturb settled law. *See Helsinn*, 855 F.3d at 1356.

The Federal Circuit appeared at first to reject a broad resolution of the parties' dispute as to whether the AIA changed the meaning of the on-sale bar. Stating that it was "declin[ing] the invitation by the parties to decide this case more broadly than necessary," it then discussed its prior jurisprudence, applying the previous statutory language of pre-AIA § 102(b), and found that there was no indication from the floor statements that Congress intended to overrule those prior cases. *See, e.g.*, *Helsinn*, 855 F.3d at 1370-71. The court further cautioned that interpreting the on-sale bar to require that the sale publicly disclose the specific claimed invention "would work a foundational change in the theory of the statutory on-sale bar."[2]

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[2] Notably, the Federal Circuit's reluctance to interpret the amended language of § 102(a)(1) as changing the law ignores that statutory upheaval is precisely what Congress intended by enacting the AIA. *See generally* John Villasenor, *The Comprehensive Patent Reform of 2011: Navigating the Leahy-Smith America Invents Act*, Policy Brief No. 184, Brookings Institution (Sept. 2011) (the AIA "constitutes the most significant overhaul of the American patent system in decades"); 157 CONG. REC. S1362 (daily ed. Mar. 8, 2011) (statement of Senator

Yet, despite its expressed reticence, the Federal Circuit went further and found that "[i]n stating that *the invention must be available to the public* [Congress] evidently meant that *the public sale itself* would put the patented product in the hands of the public." *Id.* at 1371 (emphasis added).[3] Thus, despite stating that it would not decide whether the AIA changed the meaning of the on-sale bar, as was argued by the parties and *amici* below, the Federal Circuit arrived at its own, new interpretation of the AIA based on certain floor statements of Congress and categorically held: "We conclude that, *after* the AIA, if *the existence of the sale is public*, the details of the invention need not be publicly disclosed in the terms of sale" in order for the sale to be invalidating. *Id.* at 1368, 1371. The court then held that "both the pre-AIA and AIA on-sale bars apply" to the agreement in this case. *Id.* at 1371. *See also id.* at 1369 (distinguishing prior cases and legislative intent because "[h]ere, the existence of the sale—*i.e.*, the Supply and Purchase Agreement between Helsinn and MGI—was publicly announced in MGI's 8-K filing with the SEC").

Leahy) (the AIA provides "the first meaningful, comprehensive reforms to the nation's patent system in nearly 60 years"); 157 CONG. REC. S1495 (daily ed. Mar. 9, 2011); 157 CONG. REC. H4429 (daily ed. June 22, 2011).

[3] The Federal Circuit similarly conflated cases concerning the "public sale" of an invention (whereby the *invention* is placed in the public domain) with instances where the invention is kept secret, but the existence of an otherwise confidential or private sale regarding the invention "is made public." *Helsinn*, 855 F.3d at 1369-70 (citing *Pennock v. Dialogue*, 27 U.S. 1, 19 (1829)).

The Federal Circuit's analysis, on the one hand, of multiple factors regarding the pre-AIA on-sale bar and its broad decree, on the other hand, concerning the sole factor of the mere *existence* of a sale after the AIA thus raises serious questions as to the application of the on-sale bar going forward. It is unclear based on the decision whether the pre-AIA framework—where public disclosure "is just one of several factors for determining whether the transaction rises to the level of a commercial sale"—would control the analysis, or whether, as suggested by the Federal Circuit's *sua sponte* interpretation of Congress's intent, "*the public sale itself* would put the patented product in the hands of the public" *after* the AIA. *Compare Helsinn*, App. Nos. 2016-1284, -1787 (O'Malley, J., concurring), slip op. at 3, *with Helsinn*, 855 F.3d at 1371 (emphasis added).

Judge O'Malley attempted to soften the Federal Circuit's language in her later concurrence in support of the court's denial of *en banc* review. *See Helsinn*, App. Nos. 2016-1284, -1787 (O'Malley, J., concurring), slip op. at 2-4. Citing back to the Federal Circuit's interpretation of the pre-AIA on-sale bar in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016), Judge O'Malley clarified that the "single factor" of the confidentiality of the sale "is not dispositive of the analysis." *Id.* at 3. Judge O'Malley also stated that the Federal Circuit's decision had been limited, and that all it held "was that the *particular* agreement at issue triggered the on-sale bar, in part—but not exclusively—because it was made public." *Id.* (emphasis in original). As support, Judge O'Malley noted that "Helsinn did not just disclose the fact that it had entered into a supply agreement with MGI" and further

pointed to the Federal Circuit's discussion of other information that had been disclosed by the 8-K SEC filing, including that a partially-redacted copy of the agreement itself had been included with the filing, that the agreement described the claimed drug formulation in detail, and that the agreement expressly contemplated the passage of title. *Id.* (citing *Helsinn*, 855 F.3d at 1361, 1364, 1366).

Unfortunately, Judge O'Malley's reliance on the Federal Circuit's consideration of the additional information contained in the agreement that was disclosed by the 8-K filing is directly contrary to the Federal Circuit's own conclusion that, in the post-AIA world, "if the existence of the sale is public, *the details of the invention need not be publicly disclosed in the terms of sale*" in order for the sale to trigger the on-sale bar. *Helsinn*, 855 F.3d at 1368, 1371 (emphasis added). Thus, the very information that Judge O'Malley asserted was relevant to the case and "weighed strongly in favor of finding that the on-sale bar was triggered" is precisely what the Federal Circuit held is no longer necessary post-AIA if the existence of the sale itself is made public.

Accordingly, because of the Federal Circuit's unusual emphasis on the public disclosure of the existence of a sale, rather than the disclosure of the claimed invention by the sale, the scope of the on-sale bar after the AIA has been left open and indefinite. This Court should thus grant review to clarify the applicability of the on-sale bar in view of the amended language of § 102(a)(1).

II. CLARIFICATION OF THE FEDERAL CIRCUIT'S DECISION IS VITAL TO INNOVATION AND COLLABORATION IN THE BIOTECHNOLOGY SPACE.

The need for clarification concerning the scope of the AIA on-sale bar is of critical importance to industries where pre-marketing transactions and collaboration are essential for success. The uncertainty created by the Federal Circuit's decision has a particular chilling effect on innovation and collaboration within the biotechnology industry.

Biotechnology largely remains a small company industry, and the cost of biotech development is incredibly high. On average, it takes 10 to 15 years and approximately $2.6 billion to successfully bring a new drug to market—more than double the cost during the 1990's and early 2000's. *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D costs*, 47 J. HEALTH ECON. 20-33 (2016). Because many biotechnology companies operate without revenue, these costs represent significant challenges to companies seeking market entry. *See* Lisa Eckelbecker, *Biotech Startups Face Bigger Funding Challenges Than Other Industries*, TELEGRAM & GAZETTE, June 19, 2016, http://www.telegram.com/news/20160619/biotech-startups-face-bigger-funding-challenges-than-other-industries (noting the struggles of biotech companies in securing funding and one company's solution to "develop compounds up to the point that he could license something to a pharmaceutical company for the preclinical studies that lead to human testing").

Notwithstanding the funding challenges, however, small and midsize biotechnology companies have proven

to be leaders in researching and developing breakthrough therapies and cures. *See* HBM Partners, *Trends in US New Drug Approvals* (Jan. 2018) at 1 ("As in previous years, the majority (76%) of NMEs approved in 2017 originated from smaller or mid-sized biopharma companies, *i.e.* companies outside of the 30 largest biopharma firms."). Because "these smaller companies often out-license their drug candidates or were acquired themselves before approval, the number of approvals under their name" —18 in 2017—actually "understates their important contribution to pharmaceutical innovation." *Id.* at 10.

As an example, Massachusetts is the nation's leading state for biotechnology innovation, with over 34,000 jobs classified as Biotechnology Research and Development—more than any other state. *See* MassBio, *Industry Snapshot 2017*, at 3, http://files.massbio.org/file/MassBio-Industry-Snapshot-2017.pdf. However, of the over 600 member companies of *Amicus*, at least 88% have less than 250 employees worldwide, and 74% have less than 50. Many have no revenue. Yet, Massachusetts researchers are currently researching and developing products for patients with over 380 different medical indications, including various cancers, neurological conditions, immune disorders, Alzheimer's, and diabetes. *Id.* at 25. As of 2017, Massachusetts's biotechnology drug development pipeline made up roughly one-fifth of the total U.S. drug pipeline. *Id.* at 23.

Because of the high cost of drug development and the limited resources available to most small and midsize biotechnology companies, these companies tend to rely on business partners to support their

research and development. In the case of Helsinn, and many similarly-situated companies, entering into distribution or supply agreements with a partner is necessary to obtain sufficient upfront funding to advance pipeline products through clinical trials and to gain access to critical expertise that these small companies cannot, as a practical matter, develop themselves. *See Helsinn*, App. Nos. 2016-1284, -1787 (O'Malley, J., concurring), slip op. at 12. However, if a potential business partner is a public company and required to disclose the existence of such transactions, under the Federal Circuit's decision, such a disclosure (even without any meaningful disclosure of the underlying technology that is the subject of the transaction) could cost the innovating company its patent rights. This uncertainty about what actions trigger the "on-sale" bar puts biotechnology companies in an untenable situation to choose between ensuring patent protection for their inventions (often the most valuable business assets they own) or being able to develop and commercialize their products.

The Federal Circuit has previously held that, under pre-AIA § 102(b), "[t]here is no room in the statute and no principled reason raised by the parties or any of the amici to apply a different set of on-sale bar rules to inventors depending on whether their business model is to outsource manufacturing or to manufacture in-house." *Meds. Co.*, 827 F.3d at 1378-79. The court appeared to acknowledge then the danger of "penalizing a company for relying, by choice or by necessity, on the confidential services" of another company in assisting with the development of life-saving medicines. *Id.* The Federal Circuit's apparent expansion of the scope of the AIA's on-sale bar in this case walks

squarely into that danger and has created a chilling effect that disproportionately harms small and midsize biotechnology companies. This Court should thus accept this case for review in order to resolve the uncertainties created by the Federal Circuit's decision below.

CONCLUSION

For the foregoing reasons, *Amicus* respectfully requests that this Court grant the petition for a writ of certiorari.

Respectfully submitted,

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APRIL 2, 2018

No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD.

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* THE NAPLES ROUNDTABLE IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae The Naples Roundtable, Inc. is a 501(c)(3) non-profit organization whose primary mission is the exploration of ways to improve and strengthen the U.S. patent system. To achieve this goal, the Naples Roundtable supports the advanced study of both national and international intellectual property law and policy. The Naples Roundtable fosters the exchange of ideas and viewpoints among the leading intellectual property experts and scholars. It also organizes conferences and other public events to promote the development and exchange of ideas that improve and strengthen the U.S. patent system.

More information about the Naples Roundtable can be found on the organization's website: http://www.thenaplesroundtable.org. None of the Naples Roundtable, the individuals on its Board of Directors, or its counsel have any personal interest in the outcome of this case.

REASONS FOR GRANTING THE PETITION

The petition for certiorari establishes by itself the reasons the petition should be granted. *Amicus curiae* submits this brief to expand on two particular points that warrant expanded attention.

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1. All parties have consented to the filing of this brief in letters on file with the Clerk of Court, and the parties were notified of *amicus curiae*'s intention to file this brief at least 10 days prior to the filing of this brief. *See* Sup. Ct. R. 37.2(a). No counsel for a party has authored this brief in whole or in part, and no person other than amici curiae, their members, and their counsel has made a monetary contribution to the preparation or submission of this brief. *See* Sup. Ct. R. 37.6.

First, the Federal Circuit's approach to statutory construction in this case illustrates the appeals court's failure to properly consider the explicit statutory purpose when construing the statute. Statutory text remains paramount, of course, but a statute's purpose cannot be overlooked when a court also examines other interpretative evidence in order to construe the statute.

In certain instances, as here, Congress memorializes the purpose of legislation by including one or more "sense of Congress" provisions. When Congress includes such a "sense of Congress" provision, and when that "sense of Congress" speaks directly to the interpretative question, then a court should consider this evidence of legislative purpose when construing the statute. This Court and other courts have done so in the past, recognizing that a "sense of Congress" provision is strong evidence of the legislative purpose of the statute.

Second, the Federal Circuit's erroneous construction overlooked two explicit statutory "sense of Congress" provisions, setting forth the purpose of the statute. By overlooking these explicit statements, the Federal Circuit adopted an incorrect interpretation of the statute—one that impedes the statutory objectives Congress sought to achieve when it passed the Leahy-Smith America Invents Act of 2011 ("AIA"), Pub. L. No. 112–29, 125 Stat. 284.

Within the AIA are two "sense of Congress" provisions that expressly state the objectives and policies of the legislation. Behind the first-inventor-to-file regime, as embodied in revised 35 U.S.C. § 102, were Congress's expressly stated objectives of achieving both (1) "harmonization of the United States patent system"

with those commonly used throughout the world and (2) "greater certainty regarding the scope of protection" provided by U.S. patents. AIA §§ 3(o), 3(p). Regarding the first objective, because the vast majority of patent applications filed outside the United States are filed in jurisdictions where secret commercialization is not regarded as prior art, the elimination of this category of prior art brings the U.S. patent system in line with the rest of the world. As for the second objective, the AIA's creation of greater patent certainty was intended by Congress to occur by making it easier to determine what is or is not prior art without resorting to expensive discovery, and fits logically within the policy framework of a first-inventor-to-file system. Both of these legislative objectives are furthered by limiting the scope of prior art under § 102 to that which makes the claimed invention itself "available to the public." Both objectives are thwarted, however, by the Federal Circuit's erroneous interpretation of that section of the Patent Act.

I. The Correct Statutory Interpretation Must Consider The Legislative Purpose And The "Sense Of Congress" Provisions

Congress's "authoritative statement is the statutory text, not the legislative history." *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005); *see also Hoffman Plastic Compounds, Inc. v. NLRB*, 535 U.S. 137, 149–50 n.4 (2002); *Park 'N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 (1985) ("Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose."). For this reason, "the words of a governing text are of paramount

concern, and what they convey in their context is what the text means." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 441 (2012). The obligation of the courts is thus to interpret the statute as written. *See Burrage v. United States*, 134 S. Ct. 881, 892 (2014) ("The role of this Court is to apply the statute as it is written—even if we think some other approach might accord with good policy.").

Even so, a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *accord Sturgeon v. Frost*, 136 S. Ct. 1061, 1070 (2016). A word's meaning exists only in the context in which the word is used. *See Deal v. United States*, 508 U.S. 129, 132 (1993) (explaining the "fundamental principle of statutory construction (and, indeed, of language itself)" is that "the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used").

Legislative text is not always clear. *See, e.g., Utility Air Regulatory Group v. EPA*, 134 S. Ct. 2427, 2441 (2014) (noting that the Clean Air Act "is far from a *chef d'oeuvre* of legislative draftsmanship"); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 679 (1990) ("No interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship."). When the text is unclear or subject to multiple interpretations, courts will and should routinely consider other evidence, such as the legislative purpose of the statute.

This Court and others have regularly turned to statutory purpose to ensure that the correct interpretation is reached.

> We believe it fundamental that a section of a statute should not be read in isolation from the context of the whole Act, and that in fulfilling our responsibility in interpreting legislation, "we must not be guided by a single sentence or member of that sentence, but [should] look to the provisions of the whole law, and to its object and policy."

Richards v. United States, 369 U.S. 1, 11 (1962) (quoting *Mastro Plastics Corp. v. NLRB*, 350 U.S. 270, 285 (1956)); *see also* 1A Norman Singer & J.D. Shambie Singer, *Statutes and Statutory Construction* § 25:3 (7th ed. 2008) ("The statute should be construed according to its subject matter and the purpose for which it was enacted.").

On occasion, the objective and policy behind a statute are readily discernible because Congress explicitly stated as much in provisions describing the "sense of Congress." A "sense of Congress" provision will frequently state what Congress wanted to accomplish with the particular legislation. The current U.S. Code is replete with "sense of Congress" provisions. *See, e.g.*, 2 U.S.C. § 1511(a); 5 U.S.C. § 9701(f)(1); 15 U.S.C. § 2221(l)(1); 21 U.S.C. § 1961(a).

This Court and other courts have turned to and relied on "sense of Congress" provisions when interpreting statutes. In *Accardi v. Pennsylvania Railroad Co.*, 383 U.S. 225 (1966), the Court addressed whether a former employer had improperly denied World War II veterans

their seniority rights guaranteed by the Selective Training and Service Act of 1940. The Court looked to the statute's language, noting that it "clearly manifests a purpose and desire on the part of Congress to provide as nearly as possible that persons called to serve their country in the armed forces should, upon returning to work in civilian life, resume their old employment without any loss because of their service to their country." *Id.* at 228. This "continuing purpose of Congress," as the Court observed, was further established by a "sense of Congress" provision that spoke directly to the protection of employment rights to veterans returning to civilian life. *Id.* at 229.

Courts of appeals have similarly relied on "sense of Congress" provisions when interpreting statutes. *See Hanson v. Espy*, 8 F.3d 469, 476 (7th Cir. 1993) (relying on a "sense of Congress" provision to support the interpretation of the Disaster Assistance Act of 1988); *United States v. Ellis*, 714 F.2d 953, 955–56 (9th Cir. 1983) (relying on a "sense of Congress" provision when interpreting the Consolidated Farm and Rural Development Act of 1961). While a "sense of Congress" provision may not always be controlling, it "can be useful in resolving ambiguities in statutory construction" and in reinforcing the meaning of the law. *State Highway Comm'n v. Volpe*, 479 F.2d 1099, 1116 (8th Cir. 1973).

Of course, a "sense of Congress" provision does not always create legal rights. The plain text of the "sense of Congress" statement may use non-mandatory language, such as the word "should." *See, e.g., Monahan v. Dorchester Counseling Ctr., Inc.*, 961 F.2d 987, 994–95 (1st. Cir. 1992) (holding as non-binding a "sense of Congress" that

each state "should" review and revise its laws to ensure services for mental health patients); *Yang v. Cal. Dep't of Social Servs.*, 183 F.3d 953, 958–61 (9th Cir. 1999) (explaining that the "sense of Congress" that Hmong and other Lao refugees who fought in Vietnam war "should" be considered veterans for purposes of receiving certain welfare benefits). Or the "sense of Congress" provision is issued in a non-binding House or Senate Resolution.

But in other cases, such as here, the "sense of Congress" provision is very likely the best evidence of what the statutory text was intended to achieve. This Court has long examined the "sense of Congress" when understanding the purpose of legislation and construing the terms of the legislation—even in the absence of a formal "sense of Congress" provision. *See, e.g., Nat'l Cable Television Ass'n, Inc. v. United States*, 415 U.S. 336, 337 (1974) (relying on a "sense of Congress" provision in the Independent Offices Appropriation Act of 1952); *see also Cameron Septic Tank Co. v. Knoxville*, 227 U.S. 39, 50 (1913) (holding that it was "certainly the sense of Congress" that the Treaty of Brussels of December 14, 1900 did not affect the expiration of a U.S. patent); *McClurg v. Kingsland*, 42 U.S. 202, 207 (1843); *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 218 (1824). These examples and others confirm the objective of statutory interpretation—understanding the meaning of the statute in the context of the statutory scheme and legislative purpose.

In short, a "sense of Congress" provision is often a highly probative interpretative guidepost, which a court tasked with construing a statute should consider. Yet, the Federal Circuit expressed no consideration of the two "sense of Congress" sections included in the AIA.

The two "sense of Congress" provisions in the AIA speak directly to the issue of Congress's intent in adopting a first-inventor-to-file regime, as embodied in revised 35 U.S.C. § 102. As Petitioner explains, the Federal Circuit incorrectly focused on certain floor statements instead of the statute's text.

This error was compounded when the Federal Circuit overlooked the two "sense of Congress" provisions in the AIA. The two provisions are the strongest evidence—beyond the text of § 102(a)(1) and the accompanying House Committee Report No. 112-98 (2011)—about what Congress intended when it enacted the AIA. Instead of considering the "sense of Congress" provisions, the Federal Circuit looked to—and dismissed the value of—certain floor statements by several members of Congress. The court's error was to look to only these floor statements and not consider the "sense of Congress" provisions. The incomplete consideration of the interpretative evidence is not a correct method of construing statutes. It leads to a misinformed view of legislative purpose. As explained below, in the present case, the Federal Circuit adopted a construction of the AIA that is directly undermined by the "sense of Congress" provisions.

II. The Federal Circuit's Ruling Incorrectly Overlooked The Explicit Legislative Purpose Of The America Invents Act

In the present case, the Federal Circuit's interpretation of 35 U.S.C. § 102(a)(1), as enacted by the AIA, is directly in tension with Congress's stated purpose for enacting the AIA. The purpose of the legislation is set forth in two "sense of Congress" provisions. In the first, Congress

stated its intent was to harmonize U.S. patent law with "the patent systems commonly used in nearly all other countries" by converting the U.S. patent system from a first-to-invent system to a first-to-file system. In the second provision, Congress stated its intent was to provide "greater certainty regarding the scope of protection." Both provisions underscore Congress's affirmative decision to eliminate the category of so-called "secret prior art," that is, any sales and uses that do not make the *subject matter defined by a claim in a patent or an application for patent* available to the public, as the term "claimed invention" is defined in 35 U.S.C. § 100(j).

A. Abrogating Non-Disclosing Sales and Uses as Prior Art is Consistent with Congress's Stated "Harmonization" Goal

One purpose of the AIA was to harmonize U.S. patent law with the patent systems of other major countries. This purpose is expressly stated in the AIA:

> SENSE OF CONGRESS. —It is the sense of the Congress that converting the United States patent system from "first to invent" to a system of "first inventor to file" will improve the United States patent system and promote harmonization of the United States patent system with the patent systems commonly used in nearly all other countries throughout the world with whom the United States conducts trade and thereby promote greater international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries.

AIA § 3(p).

Because Congress enacted 35 U.S.C. § 102 with the express intention of harmonizing U.S. law with foreign patent systems, the Federal Circuit should have considered what the other major patent systems in the world require for prior art in order to determine which interpretation of § 102 best accords with Congress's intent in enacting that section.

The top five national intellectual property offices are the European Patent Office, the Japan Patent Office, the Korean Intellectual Property Office, the State Intellectual Property Office of the People's Republic of China, and the United States Patent and Trademark Office. These five intellectual property offices collaborate as the "IP5," which is "a forum of the five largest intellectual property offices in the world that was set up to improve the efficiency of the examination process for patents worldwide."[2] The national patent offices of the IP5 "handle about 80 per cent of the world's patent applications, and 95 per cent of all work carried out under the Patent Cooperation Treaty (PCT)."[3]

Examining the foreign patent systems would have revealed that in all major jurisdictions in the world, a sale or use of an invention does not constitute prior art unless the *invention itself* was available to the public. In none of these jurisdictions is it sufficient that the mere fact of the sale was public when the details of the claimed invention were not publicly available. If the Federal Circuit's decision is allowed to stand, the United States will be the outlier among the IP5, despite the AIA's stated objective

2. *See* http://www.fiveipoffices.org/about.html.

3. *Id.*

of harmonizing this country's patent laws with the rest of the world. *See* Mark Schafer, *Note, How the Leahy-Smith America Invents Act Sought To Harmonize United States Patent Priority with the World, a Comparison with the European Patent Convention*, 12 Wash. U. Global Stud. L. Rev. 807 (2013).

1. Europe

Examination of patent applications in Europe is governed by the European Patent Convention, formerly known as Convention on the Grant of European Patents ("EPC"). Article 54(2) of the EPC recites:

> The state of the art shall be held to comprise everything made *available to the public* by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

(emphasis added).

The European Patent Office has issued examination guidelines that further establish that non-public use or sale of the invention does not constitute prior art. One section of the guidelines, reproduced below, highlights the European rule that the use of an invention must be public in order to qualify as a bar to patenting.

> 7.2.2 Agreement on secrecy
>
> The basic principle to be adopted is that subject-matter has not been made available to the public by use or in any other way if there is an express or tacit agreement on secrecy which has not been broken.

> In order to establish whether there is a tacit agreement, the division must consider the particular circumstances of the case, especially whether one or more parties had an objectively recognisable interest in maintaining secrecy. Important aspects in this regard are, inter alia, the commercial relationship between the parties (e.g. parent company and subsidiary, good faith and trust, joint venture or ordinary commercial transaction) and the exact object of the purported secrecy agreement (e.g. test specimens or parts for serial production).
>
> A party alleging that subject-matter was not made publicly available due to an express or tacit agreement on secrecy must substantiate and, if contested, prove this allegation. A party alleging that an undisputed or proven agreement on secrecy was broken must substantiate and, if contested, prove this allegation.

European Patent Office, Guidelines for Examination in the EPO, Part G IV-7.2.2 (Nov. 2017).[4]

2. China

The patent laws of China similarly require public use or sale of the invention in order for that activity to qualify as a bar to patenting.

Article 22.1 of the Patent Law of the People's Republic of China establishes the patents can issue only for those

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4. https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_iv_7_2_2.htm

inventions that "are novel, creative and of practical use."[5] These requirements are similar to the U.S. requirements of novelty, nonobviousness, and utility encoded in 35 U.S.C. §§ 102, 103, and 112, respectively. Article 22.2 defines "novelty" to "mean[] that the invention or utility model concerned is not an existing technology."

Article 22.5 then states: "For the purposes of this Law, existing technologies mean the technologies known to the public both domestically and abroad before the date of application." This provision thus establishes that an invention lacks "novelty" only if it was "known to the public."

The examination guidelines for patent applications under Chinese law confirm this view. Section 2.1 of the Chinese guidelines, titled "Prior Art," provide:

> According to Article 22.5, the prior art means any technology known to the public before the date of filing in China or abroad. The prior art includes any technology which has been disclosed in publications in China or abroad, or has been publicly used or made known to the public by any other means in China or abroad, before the date of filing (or the priority date where priority is claimed).
>
> The prior art shall be the technical contents that are available to the public before the date

5. An English-version of the Patent Law of the People's Republic of China is available on the website of the State Intellectual Property Office of the People's Republic of China. *See* http://english.sipo.gov.cn/lawpolicy/patentlawsregulations/915574.htm.

> of filing. In other words, the prior art shall be in such a state that it is available to the public before the date of filing and shall contain such contents from which the public can obtain substantial technical knowledge.
>
> It should be noted that technical contents in the state of secrecy are not part of the prior art. The state of secrecy includes not only the situation where the obligation to keep secret arises from regulations or agreements regarding confidences but also the situation where the obligation to keep secret arises from social customs or commercial practices, that is, from implicit agreements or understandings.
>
> However, if a person having the obligation to keep secret breaches the regulation, agreement, or implicit understanding, rendering the technical contents disclosed and making the technologies available to the public, these technologies shall form part of the prior art.

State Intellectual Property Office of the People's Republic of China, Guidelines for Patent Examination 171-72 (2010).[6]

The Chinese guidelines also explain that a "[d]isclosure by use means that by use the technical solution is disclosed or placed in the state of being available to the public." *Id.* at 173. The disclosure must be one through which "the relevant technical content is placed in such a state that the public can know it if they wish, disclosure by use can be established, and it is of

6. http://www.sipo.gov.cn/zlsqzn/sczn2010eng.pdf

no relevance whether the public had actually known it." *Id.* If "at an exhibition or demonstration of a product no explanation of the technical contents thereof is provided so that the structure and function or compositions of the product is not known to person skilled in the art, the exhibition or demonstration does not constitute a disclosure by use." *Id.*

3. Republic of Korea

Along the same lines, the patent laws of the Republic of Korea, *i.e.*, South Korea, require public disclosure in order to rise to the level of a patent-barring event. A non-public use or sale will not foreclose patenting of a novel invention in South Korea. *See* Jay Erstling & Ryan Strom, *Korea's Patent Policy and Its Impact on Economic Development: A Model for Emerging Countries?*, 11 San Diego Int'l L.J. 441, 450–51 (2010) (describing the Korean Patent Act as "provid[ing] that an invention has novelty unless it is publicly known, used, or described in a 'distributed publication' or published through 'telecommunication means'").

Article 29 of the South Korea Patent Act sets forth the requirements of patentability. Article 29(1).1 prohibits patents on "[i]nventions publicly known or worked in the Republic of Korea or in a foreign country prior to the filing of the patent application." Patent Act (Act No. 950, as amended up to Act. No. 14112), art. 29(1) (2016) (S. Kor.).[7]

The guidelines applying South Korean patent law expand on what is meant by "publicly known":

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7. http://www.kipo.go.kr/upload/en/download/PATENT_ACT_2016.pdf.

> A "publicly known" invention means an invention the contents of which have been known to an unspecified person without obligation of secrecy in the Republic of Korea or a foreign country prior to the filing of the application. The time of filing in the "prior to the filing of the application" refers to the exact point of time of filing, even to the hour and minute of the filing (if the invention is publicly known, the time is converted into Korean time). It does not mean the concept of the date of filling. "Unspecified persons" refers to the general public who does need to abide by secret observance duty.

Korean Intellectual Property Office, Patent Examination Guidelines 208–09 (July 2013)[8]; *see also* Korean Intellectual Property Office, Understanding the Patent Act of the Republic of Korea 49 (2017) ("If an invention is disclosed to a person who is obligated to keep it confidential, it is not public knowledge.")[9].

Similarly, the Korean patent guidelines describe what is meant by "publicly worked" and when an invention cannot be patented because it has been "publicly worked."

> A "publicly worked" invention means an invention which has been worked under the conditions where the contents of the invention are to be publicly known or can potentially be publicly known in the Republic of Korea

8. http://www.kipo.go.kr/upload/en/download/patent_examination_guidelines_2013_07.pdf

9. https://tinyurl.com/UnderstandingKoreaPatentAct

> or a foreign country (Definition of "working" refers to the Patent Act Article 2). Also, "being public" means a situation where it is no longer kept in secret. So, even when a small fraction of inner part of an invention is kept in secret with regard to working of the invention, it shall not be considered as a publicly worked invention.

Korean Intellectual Property Office, Patent Examination Guidelines, *supra*, at 209.

4. Japan

Finally, Japanese patent law applies the same approach to public use and sale as the other IP5 countries. Article 29(1) of the Japanese Patent Act establishes the requirements for patentability:

> An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention, except for the following cases:
>
> (i) inventions that were publicly known in Japan or a foreign country prior to the filing of the patent application;
>
> (ii) inventions that were publicly worked in Japan or a foreign country prior to the filing of the patent application; or
>
> (iii) inventions that were described in a distributed publication, or inventions that were made publicly available through an

> electric telecommunication line in Japan or a foreign country prior to the filing of the patent application.

Patent Act (Act No. 121 of April 13, 1959, as amended up to Act No. 36 of May 14, 2014), art. 29(1) (1959) (Japan).[10] Japanese law uses the same phrases "publicly known" and "publicly worked" as South Korean patent law.

The guidelines for patent examination under Japanese law expand upon the meanings of "publicly known" and "publicly worked":

> 3.1.3 Publicly known prior art (Article 29(1)(i))
>
> "Publicly known prior art" means prior art which has become known to anyone as an art without an obligation of secrecy (Note).
>
> (Note) Prior art disclosed by a person on whom obligation of secrecy is imposed to another person who are not aware of its secrecy is "publicly known prior art" irrespective of the inventor's or applicant's intent to keep it secret. Generally, an article of academic journal would not be put in public view even if it was just received. Therefore, prior art described in the article is not "publicly known prior art" until the article is published.

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10. http://www.wipo.int/edocs/lexdocs/laws/en/jp/jp198en.pdf).

> "Publicly known prior art" often become known in lecture, briefing session and so on generally. In this case, the examiner specifies the prior art on the basis of the matters explained in the lecture, briefing session and so on. In interpreting the explained matters, the examiner may use the matters derived by a person skilled in the art as a base for specifying "publicly known prior art" by considering the common general knowledge at the time of the lecture, briefing session and so on.

Japanese Patent Office, Examination Guidelines for Patent and Utility Model in Japan, Part III, ch. 2, § 3, at 6 (2015).[11] This guidance is similar to the guidance under the patent laws of Europe, China, and South Korea.

B. Abrogating Non-Disclosing Sales and Uses as Prior Art is Consistent with Congress's Stated Goal of Achieving Greater Certainty Regarding the Scope of Patent Protection

Another goal of the AIA was to increase certainty in the scope of legal protection provided by issued patents. Congress's objective was set forth in one of the two "sense of Congress" provisions included in the AIA.

> SENSE OF CONGRESS.—It is the sense of the Congress that converting the United States patent system from "first to invent" to a system of "first inventor to file" will promote

11. https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/ files_guidelines_e/03_0203_e.pdf

> the progress of science and the useful arts by securing for limited times to inventors the exclusive rights to their discoveries and provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries.

AIA § 3(o).

With § 3(o) of the AIA, Congress sought to eliminate "secret" prior art that has, for decades, caused problems in the U.S. patent system. The "sense of Congress" provision in § 3(o) embodies Congress's deliberate decision to eliminate an entire area of contention and inquiry regarding the scope of confidential sales and uses as prior art. As Senator Kyl stated before passage of the AIA, this change will have particular benefit in increasing certainty and reducing litigation discovery costs:

> Public uses and sales of an invention will remain prior art, but only if they make the invention available to the public. An inventor's confidential sale of his invention, his demonstration of its use to a private group, or a third party's unrestricted but private use of the invention will no longer constitute private [*sic*, prior] art. Only the sale or offer for sale of the invention to the relevant public or its use in a way that makes it publicly accessible will constitute prior art.
>
> The main benefit of the AIA public availability standard of prior art is that it is relatively inexpensive to establish the existence of events that make an invention available to the public.

> Under current law, depositions and litigation discovery are required in order to identify all of the inventor's private dealings with third parties and determine whether those dealings constitute a secret offer for sale or third party use that invalidates the patent under the current law's forfeiture doctrines. The need for such discovery is eliminated once the definition of "prior art" is limited to those activities that make the [invention] accessible to the public. This will greatly reduce the time and cost of patent litigation and allow the courts and the [USPTO] to operate much more efficiently.

157 Cong. Rec. S5319, S5319–21 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl). This statement thus directly links Congress's stated objective in AIA § 3(o) of achieving greater certainty, with Congress's redrafting of 35 U.S.C. § 102(a)(1), limiting prior art to those sales and uses that make the invention itself available and known to the public.

Notably, the above statement of Senator Kyl refers to both categories of prior art—"offer for sale or third party use." 157 Cong. Rec. at S5320 ("Public uses and sales of an invention will remain prior art, but only if they make the invention available to the public."). The Federal Circuit's opinion below, however, dismissed Senator Kyl's floor statements because the specific examples of judicial decisions the senator mentioned would be abrogated upon enactment of § 102(a)(1) were, according to the Federal Circuit, "public use" cases, not "sale" cases. App. 38a ("The floor statements do not identify any *sale* cases that would be overturned by the amendments." (emphasis in original)). It seems trivial to quibble about the specific

cases cited by the senator on the Senate floor when the statements explicitly and unambiguously referred to both categories of prior art—"[p]ublic uses and sales." 157 Cong. Rec. at S5320; *accord* 157 Cong. Rec. S1360, S1371 (Mar. 8, 2011) (statement of Sen. Kyl) ("A contrary construction of section 102(a)(1), which allowed private and non-disclosing ***uses and sales*** to constitute invalidating prior art, would be fairly disastrous for the U.S. patent system." (emphasis added)).

Thus, the AIA's abrogation of non-disclosing uses and sales as prior art in § 102(a)(1) was an intentional policy decision, one that achieves greater certainty in the scope of prior art and decreases litigation costs.

CONCLUSION

For the above reasons and those stated in the petition, this Court should grant a writ of certiorari.

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April 2, 2018

No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA INC. AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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INTEREST OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents leading biotechnology and pharmaceutical companies devoted to discovering and developing new and improved medicines.[1] Those efforts produce the cutting-edge treatments that save, prolong, and improve the quality of the lives of countless individuals around the world every day. Over the past decade, more than 350 new medicines have been approved by the Food and Drug Administration ("FDA"). In view of the risky research and development process, which has a significant failure rate of biopharmaceutical research and development, and the substantial requirements of the FDA to demonstrate safety and efficacy of new products, those results are not obtained cheaply. In 2016 alone, PhRMA members invested an estimated $65.5 billion in discovering and developing new medicines.

PhRMA seeks to advance public policies that foster innovation in new medicines, including by ensuring adequate patent protection to enable and incentivize its members' substantial investments in

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[1] Pursuant to Rule 37.6, PhRMA affirms that no counsel for a party authored this brief in whole or in part, and that no person other than amicus, its members, or its counsel made any monetary contributions intended to fund the preparation or submission of this brief. The parties were timely notified of PhRMA's intent to file this brief and consented to its filing. A complete list of PhRMA members is available at http://www.phrma.org/about/members (last visited Apr. 2, 2018). Members include Eisai Inc., Petitioner's U.S. marketing partner for Aloxi®, the product at issue in this case, and Teva US Specialty Medicines, a corporate affiliate of Respondents. Neither Eisai, Inc. nor Teva US Specialty Medicines contributed any money to fund the preparation of this brief.

research and development. To those ends, PhRMA seeks to remove barriers that may arise in the nation's systems, including the patent laws, for protecting the intellectual property of its members — including as *amicus curiae* before this Court.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case concerns the scope of the "on-sale" bar in patent law and whether and how the Leahy-Smith America Invents Act of 2011 (the "AIA") changed that scope. Petitioner argues in its brief that the amendments Congress introduced into the statutory definition of the on-sale bar in the AIA expressly limit the bar to sales that reveal to the public the details of the invention. Present Amicus Curiae joins those arguments and points out further that this Court's precedent suggests that the on-sale bar has always been so limited.

Innovators of all stripes—from solo inventors to pharmaceutical companies contemplating investments of billions of dollars to develop new medicines—require clarity in the law to make rational decisions about developing and commercializing their inventions. That clarity has been eroded by the Federal Circuit's decision in this case, which departs from both this Court's precedent and Congress's AIA amendments which restated the limitation of the on-sale bar to public sales. It also departs from the Government's implementation of the restated limitation. The Federal Circuit's departure from this Court, Congress, and the Government has created considerable confusion and doubt in the patent community that will persist until this Court corrects the Federal Circuit's decision. Our nation's innovation economy will

continue to suffer damage in the interim. Present Amicus Curiae joins Petitioner in urging this Court to grant certiorari now to minimize that damage.

ARGUMENT

I. Review is warranted because the Federal Circuit's decision calls into question countless issued or pending patents.

Over 1 million U.S. patents have issued, and about 3 million U.S. patent applications have been filed, since the revised on-sale bar provisions of the Leahy-Smith America Invents Act of 2011 (the "AIA") took effect on March 16, 2013.[2] Many of these patents, and innumerable more to come, are now clouded with uncertainty about the scope of the on-sale bar, for the reasons laid out in the petition. The inventions described and claimed in these patents are the work of innovators from all walks of life, from solo inventors to proprietors of small companies to scientists in the R&D divisions of large companies. They unexpectedly face a new doubt, however: whether pre-filing sales of those inventions bar their patents.

The doubt is unexpected because the AIA revisions to the on-sale bar were intended by Congress, and were implemented by the Government, to limit the on-sale bar unambiguously to sales that revealed to the public the details of the invention, as explained in the Government's *amicus curiae* brief on the merits in support of Petitioner before the Federal Circuit.

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[2] Figures compiled from USPTO Performance and Accountability Report for Fiscal Year 2017, Tables 1 (p. 168) and 6 (p. 171). URL: https://www.uspto.gov/sites/default/files/documents/USPTOFY17PAR.pdf

Gov't C.A. Br. 7–8. Sales from which the nature of the claimed invention could not be determined would not trigger the on-sale bar. *Id.*

To that end, The Patent Office promulgated examination guidelines excluding such non-public sales from the on-sale bar. *Id.* at 5 (citing *Examination Guidelines for Implementing the First Inventor To File Provisions of the Leahy-Smith America Invents Act*, 78 Fed. Reg. 11,059, 11,062 (Feb. 14, 2013). Before this guidance was issued, the Patent Office followed Federal Circuit precedent that did not exclude non-public sales from the on-sale bar. The Federal Circuit's failure to exclude non-public sales from the on-sale bar was erroneous for reasons discussed in the next section of this brief.

Pharmaceutical companies and other patent applicants have been making business decisions about how to structure commercial agreements, and when to file for patents, in reliance on clear and unambiguous statements from Congress, the courts, and the Government defining what activities would—and would not—imperil their ability to patent their inventions. The Federal Circuit's abrupt and ill-considered repudiation of Congress and the Government introduces significant uncertainty into the patent system, shifting the firm ground on which stakeholders had made decisions about how to protect their valuable intellectual property.

This upheaval has thrown into doubt the validity of countless patents and patent applications subject to the AIA definition of prior art. A number of those patents may cover potentially important new medicines or other technologies. Consider a pharmaceutical company that relied on the patent statute to pursue a

research and development program for a patented drug candidate despite earlier activities that might be characterized as "sales" but did not make the claimed invention publicly available. Loss of the patent might prompt the company to abandon its research and development efforts. Or consider a company that fully discloses an invention in a patent application following an earlier non-public sale. That company now would find itself considerably worse off than if it never had filed a patent application at all; it now might get nothing in exchange for a complete disclosure of a claimed invention in the patent.

The scope of such perverse results has not yet been ascertained, but it is likely significant. It is ultimately the public that suffers the loss of important new inventions when companies abandon their development or choose trade secrecy over full disclosure in a patent. Review now can correct the Federal Circuit's error, provide the incentives and limitations that Congress carefully crafted in the AIA, and restore stability to the examination of patent applications under the AIA. If the Federal Circuit's opinion is allowed to stand, the validity questions lingering over pending and issued patents will continue to be litigated for the foreseeable future.

The issue presented by this case is of exceptional importance to companies engaged in pharmaceutical research, because they depend on patents to protect the large investments they make in R&D and must make decisions about investments in research programs years before they can market a product. The success or failure of a pharmaceutical product can rise or fall on the fate of just one or a handful of patents, so uncertainty in a patent's valuation or validity can

significantly impair a pharmaceutical company's ability to generate revenue to support the research and development of new products. And uncertainty in the definition of what kinds of commercial agreements run afoul of the on-sale bar imperils manufacturing and distribution relationships that small companies, in particular, rely on to bring products to market. This is important in an area where there are large and small companies that can be working collaboratively, as well as academic research centers.

Companies have made significant investments, engaged in costly research, filed patent applications, and structured their business dealings, in reliance on their understanding of what activities would and would not give rise to prior art that could be used against their own patents. The Federal Circuit decision upends those expectations and puts innumerable patents at risk. Companies need clear and consistent standards to structure their operations if they are to spend years and hundreds of millions of dollars in R&D developing new treatments for patients that rely on patent protection.

II. Review is warranted because the Federal Circuit misread this Court's precedent and ignored the express enactment by Congress of the AIA.

This Court's on-sale bar precedent reaches only those sales that reveal to the public the details of the invention, whereas the Federal Circuit has extended the bar to those that do not.

This case provides an ideal opportunity for this Court to rule on the scope of the on-sale bar. In present Amicus Curiae's view, the proper scope is the one

this Court's precedents point to: that the bar is limited to sales that reveal the details of the invention to the public, and not to the rule the Federal Circuit has adopted, which extends the bar to sales from which the public cannot glean the invention. Review is appropriate to correct the Federal Circuit's rule.

Petitioner's brief explains in detail how the AIA added language to the on-sale bar provision to state expressly that the bar was limited to public sales. But in fact, this Court has never held the on-sale bar to extend to non-public sales. As such, the on-sale bar was amended not to restrict it to public sales, but rather to overrule legislatively the Federal Circuit's own extension of the on-sale bar to non-public sales. Gov't C.A. Br. 7–8 ("Congress in the AIA amended the on-sale bar to correct that error and restore the historical meaning of the phrase 'on sale.'").

The restriction of the on-sale bar to public sales has been a part of U.S. patent law at least since 1829, when this Court recognized that an inventor's "voluntary act . . . in the public sale and use is an abandonment of" the patent right. *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 24 (1829). The emphasis was on abrogating the patent rights of an inventor who failed to seek timely patent protection after allowing the invention "to be publicly sold for use." *Id.* at 23–24. The contours of the on-sale bar changed little over the years, even with the most sweeping of revisions to the patent law in 1952. Gov't C.A. Br. 7 ("In the ensuing 180 years [following the enactment of the Patent Act of 1836], during which Congress repeatedly reenacted the on-sale bar without materially changing its text, the Supreme Court has reiterated that the on-sale bar encompasses only public sales."). This Court's

most recent treatment of the on-sale bar re-emphasized its public nature. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998) (recognizing the "reluctance to allow an inventor to remove existing knowledge from public use" as the basis of the on-sale bar).

The Federal Circuit nonetheless expanded the on-sale bar to non-public sales based on this Court's citation in *Pfaff* to the Second Circuit case, *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946). *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA Inc. et al*, No. 16-1284 (Fed. Cir. Jan. 16, 2018), sl. op. at 3–4 n.1 (O'Malley, Circuit J., concurring in the denial of panel rehearing) ("the Supreme Court seems to have endorsed the general principles articulated in *Metallizing*"); *see also* Gov't C.A. Br. 7–8 (tracing Federal Circuit's creation of the non-public sales rule). The Second Circuit in *Metallizing* had held that a patent to a manufacturing process was invalid over prior public sales of articles made secretly with the process. *Metallizing*, 153 F.2d at 517–18.

The Federal Circuit mistakenly assumed, however, that this Court endorsed a broader reading of the on-sale bar in *Pfaff*. This Court in *Pfaff* addressed only whether a commercial sale of an invention "ready for patenting," but not yet reduced to practice, barred the patent. *Pfaff*, 525 U.S. 66. Thus this Court's favorable citation to *Metallizing* in *Pfaff* (525 U.S. at 68) was dicta.[3] And this Court's view that the on-sale bar applies only to sales that put the public in possession of

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[3] For a summary of the facts in *Metallizing* and the subsequent development of the eponymous doctrine, see Karshtedt, D., *Did Learned Hand Get It Wrong?: The Questionable Patent Forfeiture Rule of Metallizing Engineering*, 57 Vill. L. Rev. 261 (2012).

the invention is clear from the repeated references in *Pfaff* to the "public." *E.g.*, *Pfaff*, 525 U.S. at 64 (Congressional "reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar").

Moreover, the Second Circuit in *Metallizing* recognized that its rule was contrary to that of other courts of appeal, including the Federal Circuit's own predecessor, the Court of Customs and Patent Appeals. In *Stresau v. Ipsen*, 77 F.2d 937 (CCPA 1935), the Federal Circuit's predecessor court held that a "process claim might be valid when the inventor had kept the process secret but had sold the product." *Metallizing*, 153 F.2d at 519 (citing *Stresau*).[4]

It is clear, then, that the Federal Circuit's extension of the on-sale bar to sales that do not reveal the invention to the public is an outgrowth of dicta that runs counter to this Court's binding precedent. Given the length of time this aspect of the on-sale bar has evaded review and the Federal Circuit's determination to maintain its erroneous doctrine despite legislative overrule by Congress with the AIA, review now is timely.

CONCLUSION

For the foregoing reasons and those set forth in the petition for a writ of *certiorari*, the Court should grant the petition.

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[4] The Federal Circuit adopted as binding precedent the opinions of its predecessor courts. *South Corp. v. United States*, 690 F.2d 1368 (Fed. Cir. 1982).

Respectfully submitted,

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Dated: April 2, 2018

No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A.

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Respondents

On Petition For Certiorari
To The United States Court Of Appeals
For The Federal Circuit

BRIEF FOR *AMICUS CURIAE* CONGRESSMAN LAMAR SMITH IN SUPPORT OF PETITIONER

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March 27, 2018

QUESTION PRESENTED

In addition to barring a patent claim for "lack of novelty" based on "on sale" activities under newly enacted 35 U.S.C. § 102(a)(1)—

> (1) irrespective of the person to whom such "on sale" activities are attributable and
>
> (2) irrespective of the country in which such "on sale" activities take place, but
>
> (3) only if the subject matter defined by the claim is thereby made available to the public,

does the Leahy-Smith America Invents Act also provide that the inventor of the patent will forfeit the right to obtain a valid patent claim based upon "on sale" activities—

> (1) only if such "on sale" activities are attributable to the inventor and
>
> (2) only if "on sale" activities take place in the United States, but
>
> (3) irrespective of whether the subject matter defined by the claim is thereby made available to the public?

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I. INTEREST OF *AMICUS CURIAE* [1]

Amicus Curiae Congressman Lamar Smith served as Chairman of the Committee on the Judiciary of the U.S. House of Representatives during the pendency of various patent reform bills, including H.R. 1249, 112th Congress, enacted as the Leahy-Smith America Invents Act. He was lead sponsor of the bill and managed consideration of the bill in the House through the debate on the House floor.

Amicus has no financial interest in the parties to this litigation or in the outcome of this specific case. His sole interest in this appeal is that 35 U.S.C. § 102(a)(1), as enacted under H.R. 1249, be interpreted in a manner faithful to the legislative text.

II. SUMMARY OF THE ARGUMENT

The enactment of H.R. 1249—the Leahy Smith American Invents Act—began a new era for the U.S. patent system. Through this new statute, Congress eliminated from the U.S. patent law some of its most subjective and complex patentability requirements.

Congress enacted new conditions for patentability to replace them. These new conditions for patentability emphasized a transparency, objectivity, predictability, and—above all—simplicity unattainable under standards that applied under the pre-H.R. 1249 law.

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[1] This brief was not authored, in whole or in part, by counsel for any party. No person or entity other than *Amicus curiae* or his counsel of record made a monetary contribution to the preparation or submission of this brief. Counsel of record for each of the parties received timely notice of the intent to file this brief. Each party has consented to the filing of this brief by the filing of a blanket consent.

Most importantly, the newly enacted law favored patentability standards that moved the U.S. patent statute far closer to international norms for patenting. By any reckoning, H.R. 1249 was historic patent legislation, the likes of which had not been seen in the United States since at least the Patent Act of 1836.

Congress was materially aided in its legislative journey by the efforts of the National Research Council of the National Academies of Science. After a four-year study of the patent system, the NRC made a stunning set of recommendations in a 2004 report that called for fundamentally restructuring the U.S. patent law.

Those recommendations became the blueprint for the work of Congress that began in earnest the following year and was finally completed with the introduction and passage of H.R. 1249 in 2011.

Among elements removed from U.S. patent law were features that by 2011 *were found nowhere else in the world*. The most notable among such provisions was the so-called "first-to-invent" principle where the United States stood alone on the world in granting patents based on an inventor's supposed "date of invention."

Another such globally unprecedented feature of the pre-H.R. 1249 patent law was the so-called "inventor forfeiture" bar based upon "on sale" activities that can be specifically attributed to the inventor, as well as its companion, the so-called "in public use" bar. The panel below applied this type of "on sale" forfeiture bar to invalidate Petitioner's patent. Before H.R. 1249, under this inventor-forfeiture bar, if "public use" or "on sale" activities taking place [1] *in the United States* could be [2] *attributed to the patent's in-*

ventor, then such activities could suffice to bar the inventor's patent claims, [3] *irrespective of whether the subject matter defined by the inventor's patent claims was made available to the public as a result.*

There was no dispute in the proceedings below that a different—and essentially opposite—standard applied when the same "in public use" or "on sale" activities were alleged to constitute "prior art" used to bar a patent for "anticipation" or lack of novelty. As an "on sale" prior-art bar, for example, the pre-H.R. 1249 law required that "on sale" activities attributable to anyone other than the patent's inventor could only invalidate a patent claim *if the subject matter defined by the claim was made available to the public* as a result of the "in public use" or "on sale" activities.

The panel decision can be read as simply porting both the pre-H.R. 1249 inventor-forfeiture and prior-art "on sale" bars to patenting from the old statute into the newly enacted statute, as though the newly enacted sections of the H.R. 1249 Patent Act had reenacted both of them. However, Congress did not do so.

Any fair reading of 35 U.S.C. § 102(a)(1), the relevant new statute, indicates that *there is no bar in the new statute* [1] *specific to inventor-attributable "in public use" or "on sale" activities,* [2] *only if undertaken in the United States,* before the inventor's patent was sought, particularly one that could operate [3] *irrespective of whether the subject matter defined by a claim was available to the public.* Indeed, the relevant new statutory provision contains only a single bar to patenting. This newly enacted statutory provision, as it relates to "on sale" activities, [1] is *inventor-agnostic,* [2] with no geographic restriction on

the activities that might constitute a patent bar, and [3] specifically requires the subject matter defined by the claim must be available to the public.

The only thing stated in the newly enacted statutory text with respect to "on sale" activities is that such activities invalidate a patent claim if "*the subject matter defined by a claim*" was "*on sale, or otherwise available to the public before*" the inventor's patent was sought. Self-evidently, any reading of the new statute reveals that—

(1) It contains no provision that can be read as allowing inventor-attributable "on sale" activities to be subject to any different standard from that which applies to "in public use" or "on sale" activities attributable to anyone else.

(2) It contains no provision specific to inventor-attributable "on sale" activities that would limit such a bar solely to commercialization-related activities undertaken in the United States—which is the only circumstance in which such an inventor-attributable bar could ever justify an inventor's forfeiture of the right to secure a U.S. patent.

(3) Unlike the pre-H.R. 1249 Patent Act, the comparable text of the newly enacted statute makes explicit that a *public accessibility* standard applies with respect to all "in public use" or "on sale" activities under the newly enacted statute—by virtue of the addition to the statute of the new terminal qualifier "or otherwise available to the public." The added qualifier could have no other purpose and, thus, leaves no room for doubt.

(4) Unlike the pre-H.R. 1249 Patent Act, the newly

> enacted statute defines the term "claimed invention" (a term never before defined in the Patent Act) and then uses that new defined term—together with the new "otherwise available to the public" qualifier—to remove any potential ambiguity that might have been present in the pre-H.R. 1249 Patent Act as to *what* must be made publicly accessible, *i.e.*, whereas the old statute merely stated a patent was barred for an "*invention* ... on sale *in this country*" (old 35 U.S.C. § 102(b)), the new statute states a patent is barred for a "*claimed invention* ... on sale, or otherwise *available to the public*" (35 U.S.C. § 102(a)(1)) with the term "claimed invention" defined as the "subject matter defined by a claim." (35 U.S.C. § 100(j).

Thus, the "statutory on-sale bar" referenced in the panel decision, based on activities attributable to the patent's inventor, simply cannot be found anywhere in the newly enacted statute. No reading of the new statute can contort the words in the new statute sufficiently to fit therein a separate and additional "on sale" forfeiture bar—(1) applying only to inventor-attributable activities, (2) applying only to United States activities, and (3) extending to subject matter never made available to the public.

The panel decision cannot be justified on some alternative theory that Congress may have repealed and then failed to reenact the pre-H.R. 1249 bar on inventor-attributable "in public use" or "on sale" activities through some oversight—such that a court would be justified in interpreting the new statute to rectify such an oversight. Indeed, Congress repealed not only the inventor-attributable "on sale" forfeiture bar, but repealed each of the like bars to patenting in

which an inventor's own actions before the inventor sought a patent could result in a forfeiture or loss of right to patent. None of these old statutory "loss of right to patent" provisions were reenacted into law—and all references to "loss of right to patent" were in fact removed from the newly enacted statute.

The final evidence that Congress acted through intent, rather than oversight, comes from H.R. REP. NO. 112-98, the committee report on H.R. 1249. This report explains that when Congress added the words "available to the public"—nowhere present in the pre-H.R. 1249 Patent Act—to newly enacted § 102(a)(1), it meant what it plainly said—the H.R. 1249 "on sale" bar required the subject matter defined by the claims to be publicly accessible.

Because the panel decision reflects numerous errors in statutory construction, detailed below, *the most important of which is that the panel simply failed to construe the new statute as actually written*, a grant of certiorari is needed to avoid the prospect that millions of U.S. patents over the next several years will be examined and issued—and many of them enforced—applying a now-repealed legal standard not reenacted by H.R. 1249.

III. ARGUMENT

The proceedings below before the Federal Circuit resulted in a panel decision[2] by Judge Dyk and a second opinion by Judge O'Malley, concurring in the denial of Petitioner's request for reconsideration en

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[2] *Helsinn Healthcare v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017).

banc.[3] These decisions have deficiencies, detailed below, that make a grant of certiorari necessary to assure that H.R. 1249's newly enacted 35 U.S.C. § 102(a)(1) is not errantly construed to find a special "on sale" forfeiture bar, limited to inventor-attributable "on sale" activities, that is manifestly not present in the newly enacted statute.[4]

A. As Properly Construed, H.R. 1249's Statutory "On Sale" Bar Can Invalidate A Patent Claim Only If The Subject Matter Defined By The Claim Has Become Publicly Accessible Through The "On Sale" Activities.

1. H.R. 1249's Substantial Changes To The Patent Act Require That Newly Enacted Section 102 Be Construed *De Novo*, Not As A Mere Restatement Of The Old Patent Law.

The enactment of H.R. 1249 was the capstone of

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[3] *Helsinn Healthcare v. Teva Pharmaceuticals USA, Inc.*, App. Nos. 2016-1284, -1787, J. O'Malley, concurring in the denial of panel rehearing (Jan. 16, 2018).

[4] The Question Presented in this brief was intended to lay out for the Court both the nature of the "prior art" provision that is indisputably present in the newly enacted statute and what the Court would need to determine must additionally be found in the statute in the nature of a "inventor-forfeiture" provision for Petitioner's patent to be held invalid. The Court is invited to consider whether this question more precisely and fully lays out the issue of statutory construction that would merit review by the Court.

congressional efforts over several decades[5] aimed at modernizing the U.S. patent laws. In this regard, the new law was designed as a significant departure from foundational elements of the 1952 Patent Act.

Passage of H.R. 1249 was the culmination of a six-year legislative effort to enact a collection of 2004 recommendations by the National Research Council of the National Academies of Science.[6] A central feature of the NRC-recommended reforms was adoption of the first-inventor-to-file principle. In making this transformation from the first-to-invent principle—which had been at the core of the U.S. patent system for over a century—Congress determined that:

> [C]onverting the United States ... to a system of "first inventor to file" will harmonize the United States ... with ... nearly all other countries throughout the world ... and thereby promote a greater sense of international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries."[7]

To achieve the necessary uniformity and certainty, Congress was obliged to make a fresh start with several sections of the Patent Act. This led to the repeal of 35 U.S.C. § 102 of the 1952 Patent Act addressing

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[5] See, especially, the Patent Law Amendments Act of 1984, Pub. L. No. 98–622, 98 Stat. 3383 and the American Inventors Protection of 1999, Act of 1999, Pub. L. No. 106-113, § 4001, 113 Stat. 1501, 1501A-552.

[6] National Research Council. 2004. *A Patent System for the 21st Century*. Washington, DC: The National Academies Press. https://doi.org/10.17226/10976.

[7] Sec. 3(q), Pub. L. 112-29, 125 Stat. at 293.

"Conditions for patentability; novelty and loss of right to patent" and its replacement with an entirely new section.

Like other aspects of the NRC-recommended changes to the Patent Act, the new patentability principles in the newly enacted § 102(a)(1) were calculated to effect the greater transparency and simplicity needed to foster enhanced certainty that would characterize a newly internationally harmonized patent law.[8]

H.R. 1249 reflected in many respects an opposite legislative approach from that of the 1952 Patent Act. The 1952 legislative effort was almost solely aimed at simply regurgitating long-existing patenting standards into a new version of the prior patent statutes. The best example of the redrafting (rather than reform) nature of the 1952 law can be found in the key provisions of section 102,[9] including the foundational provisions of old § 102(a) and old § 102(b) of the 1952 Patent Act.

In 1952, Congress noted in enacting these subsections that it was preserving all of the patent law that had come before, "'[n]o change is made in these para-

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[8] Robert A. Armitage, *Leahy-Smith America Invents Act: Will It Be Nation's Most Significant Patent Act Since 1790?*, Washington Legal Foundation Legal Backgrounder Vol. 26, No. 21 (September 23, 2011), p. 1, available at http://www.wlf.org/Upload/legalstudies/legalbackgrounder/09-23-11Armitage_LegalBackgrounder.pdf.

[9] A statutory reference herein without a corresponding indication of the title of the United States Code in which the statute resides refers to title 35, United States Code.

graphs other than due to division into lettered paragraphs."[10] Even when the existing law could have been better expressed in different words, Congress stuck with old expressions from the former statute, however inapt,[11] to suggest *no change whatsoever in the law that had come before.*

The exercise at construing the provisions of our Nation's new law on patentability under H.R. 1249 needs to reflect a quite different approach to statutory construction given the intent to do more than simply rewrite. Unlike what might have reflected congressional intent in 1952, Congress was not writing a new statute in 2011 in the hope that old principles of an old law could somehow be fit into the words of the new statute—even where some of the individual words in the new statute are unchanged from the old. As noted above, H.R. 1249 aimed at a new "system," reflecting both different policy values and a different approach to the manner in which the patent laws should operate to best promote progress in the useful arts.

At a minimum, therefore, the task of the panel below should have been to view with fresh eyes a new statute setting out a new and different patent law. Unlike 1952, in 2011 Congress was not imploring the courts to find that nothing had been changed from the prior statute with the repeal of old section 102 and the enactment of a replacement.

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[10] H.R. REP. NO. 82-1923 (Appendix, Revision Notes), p. 17.

[11] See H.R. REP. NO. 82-1923 (Appendix, Revision Notes), *supra*, at p. 17, *i.e.*, "The interpretation by the courts of paragraph (a) [of old section 102] as being more restricted than the actual language would suggest (for example, 'known' has been held to mean 'publicly known') is recognized but no change in the language is made at this time."

All that said, whatever else the new statute merits as it is construed by the courts, it deserves to be applied *as actually written*. Given the story behind its enactment, one imperative must be to avoid any temptation to distort what is in the new statute in an effort to see elements of an old patent law that are no longer there.

2. H.R. 1249's New Statutory Text In § 102(a)(1), *If Simply Construed As Written*, Sets Out A Single "Public Accessibility" Standard That Applies Irrespective Of Whether the "On Sale" Activities Are Attributable To The Inventor.

A simple reading of newly enacted § 102(a)(1) reveals that the panel below did not apply this new statute as written. The panel's failure to "apply as written" is the core defect in its decision.

The panel decision purports to do no more than construe a new statute, *i.e.*, what Judge Dyk's opinion references as the "statutory on-sale bar,"[12] now found in newly enacted 35 U.S.C. § 102(a)(1).[13] Thus, to get

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[12] 855 F.3d at 1369.

[13] Newly enacted 35 U.S.C. § 102(a) contains two categories of prior art often referred to as "publicly disclosed" prior art found in paragraph (1) and "patent filing" prior art found in paragraph (2), respectively. "Patent filing" prior art arises from a non-public disclosure in a patent filing that eventually publishes, either as an application or as an issued patent. Once published it exerts its effect as prior art back to its non-public, patent-filing date. The "on sale" bar arises from paragraph (1) activities. See Robert A. Armitage. *Understanding the America Invents Act and*

to the right result for this or any other "statutory" construction exercise, the holding of the court needs to align with how the statute actually reads.

Under newly enacted § 102(a)(1), a patent claim is invalid if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." In general, the "patented" and "described in a printed publication" categories for § 102(a)(1) "prior art" can be thought of as "document-based," while the remaining categories can be characterized as being "activities-based."

On its face, the new statutory "on sale" bar to patenting applies equally to all "activities-based" disclosures irrespective of the person who is the source of the actions. Indeed, because actual text of the statute cannot be construed to mean anything else, there is no possible textual justification in newly enacted § 102(a)(1) for imposing a different standard for determining whether a disclosure is or is not a bar to patenting *depending on whether or not the underlying "on sale" (or "in public use") activity in question arises from actions attributable to the inventor of the claimed invention.*

Thus, if the panel decision had been true to the statutory text, it could not have imposed an "on sale" bar based on Petitioner's own "on sale" activities that would have been any different from the bar that would have applied had the on sale activities been attributable to anyone else. Notwithstanding the plain

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Its Implications for Patenting, 40 AIPLA Q.J. 1, 22-87 (2012), available at https://www.uspto.gov/sites/default/files/aia_implementation/armitage_pdf.pdf.

meaning in the statutory text, this is precisely what the panel did.

Historically, *except for actions attributable to the inventor*, the only "on sale" (or "in public use") activities that could invalidate a patent claim for lack of novelty were those in which *the subject matter defined by the claim had become publicly accessible through those activities.*[14] For example, it is beyond dispute that had the "on sale" activities here been undertaken by the Respondent rather than Petitioner, Respondent could have relied its own "on sale" activities to invalidate the Petitioners patent claims *only to the extent those activities rendered the subject matter defined by the claims publicly accessible.* Because the "on sale" activities in question did not make the details of the claim to the invention publicly accessible, had the identical "on sale" activities *not* been attributable to the inventor, old § 102(b) would not have invalidated Petitioner's patent.

Under the pre-H.R. 1249 patent statute, inventor-attributable "on sale" activities were construed as not being held to this public accessibility requirement.[15] Thus, for inventor-attributable "on sale" activities, the details of the invention did not need to be publicly available.

This special legal rule applying only to inventor-attributable activities gives rise to what, under the

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[14] *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540 (Fed.Cir.1983),

[15] *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, (1998).

pre-H.R. 1249 law, is typically characterized as a *forfeiture* of the right to patent.[16] The old statute operates with this "forfeiture" component, as well as a companion "prior art" provision, because an inventor forfeiture rule is one that applies only to actions that can be attributable to the inventor, while prior art arises whenever non-inventor disclosures can trigger the bar.

In enacting H.R. 1249, Congress gave consideration to the fate of each the various "loss of right to patent" provisions under which the actions of the inventor before the inventor's patent filing could result in a forfeiture by the inventor of the forfeiting inventor's right to patent. Pre-H.R. 1249 section 102 contained three other such *loss of right to patent* or *forfeiture* provisions.

Old 35 U.S.C. § 102(c) provided that an inventor could "abandon" an invention and forfeit the right to patent it. Old 35 U.S.C. § 102(d) provided the same consequence if foreign patenting was undertaken by the inventor prematurely. Old 35 U.S.C. § 102(f) barred a patent if the patent applicant "did not himself invent the subject matter sought to be patented."

These "attributable to the inventor" bars were repealed once Congress repealed outright old section 102. Once repealed, none of them were reenacted through H.R. 1249.

Congress took an additional step in enacting H.R. 1249 to clarify such a full repeal had been accom-

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[16] Dmitry Karshtedt, *Did Learned Hand Get it Wrong?: The Questionable Patent Forfeiture Rule of Metallizing Engineering*, 57 Vill. L. Rev. 261 (2012), available at: http://digitalcommons.law.villanova.edu/vlr/vol57/iss2/2.

plished. Old section 102 carried the caption, "Conditions for patentability; novelty and *loss of right to patent*." Newly enacted section 102 is captioned simply, "Conditions for patentability; *novelty*." With these actions taken by Congress, nothing remains in the Patent Act to provide even the slightest hint that a "loss of right to patent" or forfeiture provision might remain based upon inventor-attributable activities.

Thus, given the foregoing context, the panel decision can be best understood as premised on an assumption, never explicitly stated in the decision, that the term "on sale" in newly enacted § 102(a)(1) can somehow have two different and essentially contradictory meanings as to what can constitute an "activities-based" bar to patenting—one meaning for inventor-attributable activities (and thereby creating an "on sale" forfeiture bar) and a second for activities attributable to anyone else (and thereby constituting a "prior art" bar under which a patent could be invalidated on anticipation or "lack of novelty" grounds). However, no possible reading of newly enacted § 102(a)(1) would provide any basis in the statute for such a bifurcated interpretation.

Indeed, comparing the new text of newly enacted § 102(a)(1) to the old § 102(b) assists in underscoring that this forfeiture aspect of old § 102(b) relating to "on sale" activities has no counterpart in the newly enacted law—

(1) Congress added a terminal qualifier in newly enacted § 102(a)(1) that did not appear in old § 102(b), such that the new statute now reads: "in public use, on sale, *or otherwise available to the public*." The addition of this qualifier hardly permits any doubt as to whether it was added for the specific purpose of underscoring that the newly enacted paragraph was to

be entirely restricted to precisely the same meaning the "on sale" bar had when patents were invalidated based on "prior art," *e.g.*, as old § 102(b) applied to "on sale" activities not inventor-attributable.

(2) Old § 102(b) included an "in this country" limitation on "in public use or on sale" activities that could result a forfeiture-type bar based upon an inventor-attributable "on sale" activities that is absent from newly enacted § 102(a)(1). Such a limitation was essential to the inventor-forfeiture bar in § 102(b) since the essence of the bar based upon inventor-attributable activities was to prevent an inventor from "gaming" the U.S. patent system—by seeking patent rights in the United States only after securing commercial benefits in the United States in the form of commercial use and/or sale of the invention for which the U.S. patent was later sought. It would have made no policy sense for Congress to have reproduced the old § 102(b) forfeiture bar in newly enacted § 102(a)(1) without also explicitly writing into the new statute that this forfeiture only applied to inventor-attributable "on sale" activities *in the United States*. Rather than reproducing the "in this country" limitation from old § 102(b) into newly enacted § 102(a)(1), either in whole or in part, Congress took the dramatic step of removing any geographic limitation from § 102(a)(1)-type prior art. This expansion of prior art represented a critical step towards further harmonizing U.S. patent law with that of other countries where "activities-based" prior art is not restricted geographically. Thus, this aspect of the newly enacted statute provides compelling evidence that the inventor-forfeiture aspect of old § 102(b) is nowhere to be found in § 102(a)(1).

(3) If Congress wished to reproduce in H.R. 1249 a

forfeiture provision based upon inventor-attributable, U.S.-based "on sale" activities, it could have explicitly done so. However, the fact that § 102(a)(1) contains no such discrete forfeiture provision—and the fact that three other like inventor-attributable bars to patenting from old section 102 were repealed without reenactment—supports the conclusion that the newly enacted statute must mean what it plainly says. When newly enacted section 102 is taken as a whole, it should be self-evident that none of the old section 102 "loss of right to patent" provisions based on inventor-attributable activities were reenacted under the new statute.

3. H.R. REP. NO. 112-98 Eliminates Any Possible Doubt Over the Proper Construction To Be Given To Newly Enacted § 102(a)(1).

Since the opinions by both Judge Dyk and Judge O'Malley contained discussions of the legislative history relevant to H.R. 1249, it would have been appropriate for the panel to have considered the most relevant committee report from the Committee on the Judiciary of the U.S. House of Representatives relating to H.R. 1249, *i.e.*, the report specific to H.R. 1249 itself. This is especially so since "[o]nly one committee report, H.R. REP. NO. 112-98 (2011), was issued by a committee during the Congress in which [H.R. 1249] was enacted."[17]

Unlike Judge Dyk, Judge O'Malley does cite to a

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[17] Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 453 (2012)

congressional committee report. However, the report Judge O'Malley addresses in her opinion related to another patent bill in an earlier Congress that originated in the Senate, not the House.[18] Neither opinion considers what is in H.R. REP. NO. 112-98.

H.R. REP. NO. 112-98, in discussing the effect of newly enacted § 102(a)(1), notes that "[p]rior art will be measured from the filing date of the application and will typically include all art that publicly exists prior to the filing date, other than disclosures by the inventor within 1 year of filing." The report continues with the observation that "the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publicly accessible."

While legislative history is not a substitute for legislation, when Congress makes a remarkable and unprecedented set of changes to the patent statute, a report such as H.R. REP. NO. 112-98 can represent the most authoritative non-textual source for understanding the intent and purpose of the statute and—as here—can reaffirm what the statute itself plainly explains is the legal standard to apply. Notwithstanding any provisions that might be found to be present in old § 102(b), H.R. REP. NO. 112-98 plainly sets out that newly enacted § 102(a)(1) is a "prior art" provision in which an overarching requirement for *public accessibility* of the "subject matter defined by a claim" is needed to bar a patent on the claim.

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[18] S. Rep. No. 111-18 (2009).

4. The Panel Decision Ignored The Directive In H.R. 1249 That The "Subject Matter Defined By The Claim" Must Be "Available To The Public" To Invalidate A Patent Claim.

The panel decision failed to take any account of a final drafting difference between old § 102(b) and newly enacted § 102(a)(1). It is a drafting difference that—together with the new "or otherwise available to the public" text—cinches the impossibility that a proper construction of newly enacted § 102(a)(1) could find that this newly enacted paragraph preserves a forfeiture element based on inventor-attributable activities.

In analyzing the newly enacted statute, Judge Dyk frames the issue that the panel is to address with the following quote from 35 U.S.C. § 102(a)(1) [emphasis appears in the quotation], "By enacting the AIA, Congress amended § 102 to bar the patentability of an 'invention [that] was patented, described in a printed publication, or in public use, *on sale*, or otherwise available to the public before the effective filing date of the claimed invention.'"

Judge Dyk's quotation from the statute begins with the word "invention," but inexplicably omits from the quotation the immediately preceding word "claimed." What is remarkable about the omission of the word "claimed" from the panel's statutory quote is that—while the term "invention" is circularly defined in the 1952 Patent Act as "invention or discovery"[19]—

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[19] 35 U.S.C. § 100(a).

the term "claimed invention"[20] is newly defined in the statute under H.R. 1249 in 35 U.S.C. § 100(j) to mean "the subject matter defined by a claim in a patent or an application for a patent." Incorporating this definition directly into newly enacted § 102(a)(1) clarifies its meaning: "on sale" activities cannot invalidate a patent claim unless *the subject matter defined by the claim was ... on sale, or otherwise available to the public.*

The plain meaning of the phrase "defined by the claim" is whatever *explains and describes the exact limits of the claim.*[21] Put into the language from Judge Dyk's opinion, the term "claimed invention" encompasses subject matter constituting the *details of the invention.*

Thus, this definition, overlooked in its entirety in the panel decision, is yet another indication that a proper construction of the entirely restructured section 102 under H.R. 1249 is simply devoid of any "loss of right to patent" provisions, including the "on sale" forfeiture that the panel applied based on old § 102(b).

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[20] Congress extensively amended the Patent Act to make use of this newly defined term and did so in the hope of bringing more precision and clarity to the statute. This defined term appeared not at all in the repealed section 102, but appears no less than 16 times in newly enacted section 102.

[21] See Oxford Living Dictionaries (US English; Online) at https://en.oxforddictionaries.com/definition/us/define, "define" means "state or describe exactly the nature, scope, or meaning of" and "mark out the boundary or limit of" and Cambridge Dictionary (UK English; Online) at https://dictionary.cambridge.org/dictionary/english/define, "define" means "to explain and describe the meaning and exact limits of something."

B. The Panel Decision Cannot Properly Be Upheld As A Matter Of Nonstatutory, Judge-Made Law Given Such A Holding Would Do No More Than Contradict What Is In The Statute Itself And Frustrate The Constitutionally Consistent Objectives Of Congress In Enacting The New Patent Law.

While the panel insisted that it was applying a "statutory on-sale bar," the panel decision could not be justified on the alternative ground that it was propounding some sort of new judge-made law—in this case by putting into the patent law something outside the statute that was essential to the proper functioning of a patent system and overlooked or unintentionally left out by Congress.

The panel's "on sale" bar (*i.e.*, its holding that § 102(a)(1) authorizes forfeiture of the inventor's right to a patent arising from an inventor's pre-patent-filing "in public use" or "on sale" activities, irrespective of whether the subject matter defined by the patent claim is publicly accessible), is clearly not a viable candidate for such a judicial intervention. *The type of bar the panel describes is not known to exist in any other patent law in any country of the world.* This alone suggests no necessity for having one.

Such unanimity outside the United States is unsurprising given that—with the enactment of H.R. 1249—there is now no country in the world that operates a patent law on the first-to-invent principle. There is today no country in the world where its patent system operates on principles where such a bar might find colorable justification policy-wise.

The policy reasoning is straightforward. The patent system promotes progress in the useful arts when it encourages inventors to disclose their inventions promptly and *discourages measures that encourage inventors to keep their inventions hidden from the public.* Under the first-inventor-to-file principle, a strong incentive exists for inventors to disclose their discoveries early, before the public disclosures or patent filings by others bar them from seeking patents. They face the possibility of new novelty and non-obviousness bars each day a patent filing is delayed, once the invention is "ready for patenting." In addition, an inventor can no longer rely on an earlier "date of invention" to retrieve an old or obvious discovery from the public domain.

With a strong incentive to promptly file for a patent in a patent system anchored to the first-inventor-to-file principle, the continued imposition of either an "in public use" or "on sale" forfeiture bar in the first-inventor-to-file world—such as the one applied by the panel—actually violates rather than vindicates the "promoting progress" objective for the patent system. Once the panel's bar takes effect, it operates as a perverse incentive to keep all the details of the invention secret—because continued secrecy becomes the only remaining form of protection against copying by others. The day-by-day continuing incentive to disclose under the first-inventor-to-file principle is, thus, nullified.

The panel decision thus fails on statutory grounds as well as fails to meet any possible threshold for the courts to act outside the statute to preserve some aspect of the old § 102(b) forfeiture as a judge-made law. All this said, the panel obviously did rely on a policy justification for its holding through its reliance on this

Court's *Pennock*[22] decision, quoting extensively from the decision in a footnote and further asserting that it could not depart from *Pennock* "without making a foundational change in the theory of the statutory on-sale bar."

The panel's reliance on *Pennock*, however, appears misplaced. It appears that in *Pennock* the *inventor's licensee* sold and *thereby made available to the public* an *article of manufacture* that, absent rights under the patent, apparently would have infringed the patent.[23]

If so, *Pennock* stands for nothing more than the incontrovertible *novelty-defeating* principle later expressed by this Court as, "That which infringes if later, anticipates if earlier."[24] The patentee was simply seeking a patent on the prior art—and, to the Court in *Pennock*, it would have been of no consequence who had sought such a patent invalid over this inventor-attributable "prior art."

Indeed, what the patentee in *Pennock* unsuccessfully attempted to convince this Court was that the *public accessibility* of the claimed invention before the patent was sought should be *disregarded* as a prior art bar precisely because the "in public use" or "on sale" activities were inventor-attributable. This Court found no such patent-saving exception in the then-applicable patent statute.

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[22] *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829).

[23] "[T]he article so publicly used, and afterwards patented, was made by a particular individual, who did so by the private permission of the inventor."27 U.S. (2 Pet.) at 15.

[24] *Peters v. Active Mfg.*, 129 U.S. 530, 537 (1889).

IV. CONCLUSION

Because the panel decision addressed—inadequately and wrongly—such a very important question arising from a singularly important effort to reform the Patent Act, this Court should grant certiorari.

Respectfully submitted,

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March 27, 2018

No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC. and
TEVA PHARMACEUTICAL INDUSTRIES, LTD.

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* US INVENTOR, INC. IN SUPPORT OF PETITIONER HELSINN HEALTHCARE S.A.'S PETITION FOR A WRIT OF CERTIORARI

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I. Interests of Amicus Curiae US Inventor, Inc.[1]

US Inventor, Inc. ("US Inventor") is a non-profit association of inventors devoted to protecting the intellectual property of individuals and small companies. It represents its 13,000 inventor and business members by promoting strong intellectual property rights and a predictable U.S. patent system through education, advocacy, and reform.

US Inventor was founded to support the innovation efforts of the "little guy" inventors, seeking to ensure that strong patent rights are available to support their efforts to develop their inventions, bring those inventions to a point where they can be commercialized, create jobs and industries, and promote continued innovation. Its members consist of individual inventors and small- to medium-sized enterprises that depend heavily on the value created by meaningful patent rights. Their broad experience with the patent system, new technologies, and creating companies, gives them a unique perspective on the important issues presented in Helsinn Healthcare, S.A.'s petition for a writ of certiorari.

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1. Pursuant to Supreme Court Rule 37, all parties received notice of amicus curiae US Inventor's intent to file this brief 10 days before its due date. All parties to this matter have filed letters granting blanket consent to amicus curiae briefs. Amicus US Inventor certifies that no counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund preparing or submitting this brief. No person or entity, other than amicus, its members, or its counsel, contributed money intended to fund preparing or submitting this brief.

II. Summary of the Argument

This Court should grant certiorari because the Federal Circuit has decided an important question of law in a way that conflicts with the plain language of § 102(a)(1) of the America Invents Act ("AIA"), and is otherwise unsupported. The Federal Circuit's *Helsinn* opinion conflicts with the AIA's legislative history, conflicts with the USPTO's analysis and interpretation of the statute, and conflicts with prevalent canons of statutory construction. If allowed to stand, the *Helsinn* opinion will have a severe and disproportionate impact on the small U.S. inventor—the life and blood of our economy—whose interests our patent law system is supposed to foster and protect. It is critically important that this Court grant Helsinn's petition for a writ of certiorari.

III. Argument

A. The Federal Circuit's Interpretation of Section 102(a) Is Contrary to the Purpose of the AIA and Destroys Harmony with Foreign Law.

An explicit objective of the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 254 (2011) ("AIA"), was to "establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs." H.R. Rep. No. 112–98, 112th Cong., 1st Sess. (June 1, 2011) ("AIA Committee Report") at 40. A profound change effected by the AIA was the conversion of the American patent system from a "first-to-invent" to a "first-inventor-to-file" system, thereby taking a major step towards harmonizing the American patent system with the systems of other leading

industrialized countries around the world. *Id.* This change stemmed from Congress's recognition that it is "common for inventors and companies to file for protection in several countries at the same time." *Id.* at 41. An important goal of harmonization was to eliminate the need for patent applicants to comply with multiple incompatible patent systems.

As part of that harmonization, Congress redefined the scope of invalidating prior art under § 102 as follows:

> A person shall be entitled to a patent unless—
> (1) the claimed invention was patented, described in a printed publication, *or* in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention ....

AIA 35 U.S.C. § 102(a)(1) (emphasis added).[2]

A primary purpose of the "on-sale" bar is to "exclude from consideration for patent protection knowledge that is *already available to the public*" on the grounds that "the creation of a monopoly in such information would not only serve no socially useful purpose, but would in fact injure the public by *removing* existing knowledge from public use." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989) (emphasis added). By enacting the AIA and making explicit the requirement that prior

2. The redefinition of the scope of prior art is only one of the significant changes wrought by the AIA. For a comprehensive list of those changes, see R.A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q. J. 1, 10-14 (2012).

art make the claimed invention available to the public to qualify as potentially invalidating, Congress affirmed that longstanding purpose.

Construing AIA § 102(a)(1) as excluding as prior art sales that have not made the invention "available to the public" also comports with the AIA's overarching goal of "harmonizing our system for granting patents with the best parts of other major patent systems throughout the industrialized world." AIA Committee Report at 39. No other major industrialized nation defines invaliding prior art as encompassing secret sales. *See, e.g.*, Brief for The Naples Roundtable, Inc. as Amicus Curiae Supporting Plaintiffs-Appellees at 6-13, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017) (No. 2016-1284, 2016-1287). Interpreting the on-sale bar to encompass secret sales would undermine Congress's goal of ensuring that what counts as prior art under American law is consistent with prior art recognized by other nations.

Before the AIA was enacted, an invention that was "in public use" or "on sale" precluded the grant of a patent only if such public use or sale occurred "in this country." Pre-AIA 35 U.S.C. § 102(b). Prior art now encompasses "all art that *publicly exists* prior to the filing date" regardless of geographical location. AIA Committee Report at 42 (emphasis added). This geographical expansion is interconnected with the limitation of prior art to the categories of *publicly available* materials listed in § 102(a)(1), including those "in public use" or "on sale." Both the geographical expansion and the restriction of prior art to publicly available materials harmonize U.S. law with foreign law regarding the bases for invalidity. The Federal Circuit opinion, which did not address the AIA Committee Report for the enacted version of the AIA,

utterly defeats a major purpose of Congress in enacting § 102(a)(1), and renders the United States, once again, out of step with the rest of the world.

B. The "Little Guy" Stands to Bear a Disproportionate and the Most Destructive Brunt of this "On Sale" Bar Storm.

The small inventor is the true representative of the culture of innovation and ingenuity that Article I, Section 8, Clause 8 of the Constitution was meant to promote and foster. The Federal Circuit's *Helsinn* opinion effects a direct hit on this country's grassroots inventive ethos by disincentivizing the risk-taking and experimentation that are inherent in the inventive process, and creating uncertainty with respect to development and commercialization of inventions.[3]

The *Helsinn* opinion is especially problematic because it comes at a time when the United States is facing a true crisis in innovation. Countries that were once net importers of advances in technology are now eclipsing the United States with respect to advances in the industries of the future. For example, in 2017, China accounted for 48% of the world's total artificial intelligence startup funding, while the United States accounted for only 38% of such funding.[4] China is either already leading or is

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3. *See generally* P. Morinville, "Crisis in American Innovation," US Inventor, *available at* http://www.usinventor.org/wp-content/uploads/2017/08/USI-Crisis-in-American-Innovation-Full-Version.pdf.

4. *See* J. Vincent, "China overtakes US in AI startup funding with a focus on facial recognition and chips," at 1, *available at* https://www.theverge.com/2018/2/22/17039696/china-us-ai-funding-startup-comparison.

becoming the world leader in quantum computing, solar cells, and other technologies that provide the foundation for several important industries, including advanced energy production and globalized currencies.[5] These changes are reflected in the significant difference in the number of patent applications between the two countries: by 2015 nearly twice as many patent applications were filed in China (1,101,864) as were filed in the United States (589,410).[6] In the first quarter of 2017, the number of angel and seed stage funding rounds in the United States dropped 62 percent.[7] Entrepreneurs have found it harder and harder to raise money through venture capital.[8]

If allowed to stand, the Federal Circuit's opinion in *Helsinn* will cause significant irreparable harm to small inventors, who are critical to the innovation ecosystem. As

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5. *See* J. Pekkanen, "China Leads The Quantum Race While The West Plays Catch Up," at 2, *available at* https://www.forbes.com/sites/saadiampekkanen/2016/09/30/china-leads-the-quantum-race-while-the-west-plays-catchup/#b14212592856; M. Meng, "With high-performance cells, China takes aim at high-end solar market," *available at* https://www.reuters.com/article/us-china-solar-cost-analysis/with-high-performance-cells-china-takes-aim-at-high-end-solar-market-idUSKCN1BP0X6.

6. WIPO, "Global Patent Applications Rose to 2.9 Million in 2015 on Strong Growth From China; Demand Also Increased for Other Intellectual Property Rights," at 1, *available at* http://www.wipo.int/pressroom/en/articles/2016/article_0017.html.

7. *See* M. Kendall, "Silicon Valley investing slump continues, fewer startups get funded," at 4, *available at* https://www.siliconvalley.com/2017/04/04/silicon-valley-investing-slump-continues-fewer-startups-get-funded/.

8. *Id.*

of about a decade ago, they hired 43 percent of America's high tech workers (*e.g.*, scientists, engineers, computer programmers), produced 16.5 times more patents per employee than large patenting firms, generated 65 percent of net new jobs over the previous 17 years, and made up 97.5 percent of all identified U.S. exporters.[9]

Small inventors often lack the resources or manufacturing ability to develop their inventions themselves. They rely on development arrangements and seed funding to pay for the significant costs of patent prosecution and of engaging in further experimentation, discovery, and invention development. They need to be able to rely on their intellectual property rights as a basis for attracting businesses that may be interested in those innovations, and in partnering, collaborating, or investing in them. Confidential inclusion of patent rights as part of a transaction is an essential step in enabling a small inventor to bring an invention from its conception to the point where it becomes a contribution to society. Trial and error are inherent in the innovation process, and significant work may only yield a small amount of patentable, and commercially viable matter. If inventors cannot disclose their inventions under confidentiality agreements as part of their business development transactions without fear that they are thereby placing the patentability of those inventions in jeopardy, future innovation, collaboration, and development will be severely chilled.

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9. Small Business Administration, Office of Advocacy: The Voice of Small Business in Government (updated Jan. 2011), *available at* https://www.sba.gov/sites/default/files/sbfaq.pdf.

This is especially true when inventions are being developed by smaller companies, where an agreement with another company to fund or share the costs of development may rise to the level of materiality, and thus obligate such companies under federal securities laws to disclose the agreement in their public filings (as occurred in *Helsinn*). *See* 17 C.F.R. § 240.12b-2. (SEC defining "material" as those matters to which there is a substantial likelihood that a reasonable investor would attach importance in determining whether to buy or sell the securities registered). This means that the materiality threshold for including information in the SEC filings of a million-dollar company is far lower than it is for a billion-dollar company—small businesses have to disclose much smaller transactions to comply with the SEC's materiality requirement than large businesses do. Small businesses also will face difficulty in attracting and co-developing or acquiring rights to inventive ideas for development and public benefit.

In the pharmaceutical industry, drug development typically requires many years and billions of dollars.[10] In order for smaller companies to participate in the drug development process, they necessarily must partner with larger companies or venture capital funding sources. If a conveyance of rights to the invention is included as part of the collaboration agreement such that it qualifies as a "sale," *Helsinn* renders that agreement invalidating prior art, even if the invention itself is not disclosed to, or otherwise put in the hands of, the public.

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10. *See* Tufts Center for the Study of Drug Development (CSDD), "Tufts CSDD Assessment of Cost to Develop and Win Marketing Approval for a New Drug Now Published," *available at* http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published.

The Federal Circuit also injected uncertainty and unpredictability into a judicially created "existence of sale" bar by making statements such as, "We do not find that distribution agreements will always be invalidating under § 102(b). We simply find that this particular Supply and Purchase Agreement is." *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017). This particular Supply and Purchase Agreement, however, was redacted, and did not disclose the claimed invention. *Helsinn*, 855 F.3d at 1361-62.

The Federal Circuit has created a Hobson's choice for the small inventor, both alternatives of which are detrimental to innovation and against the public interest: collaborate and develop your invention but give up your patent rights by doing so (thus killing the invention, and keeping the public from benefiting from it in the process), or patent it but do not enter into the agreements necessary to develop it, and thus leave it and the patent sitting on a shelf (thus killing the invention, and keeping the public from benefiting from it in the process).

Small inventors face numerous challenges and obstacles these days, and a dependable and clear patent protection framework is an essential foundation for them to be able to survive and thrive. They need this Court to address and reverse the *Helsinn* opinion, before it and its progeny cause irreparable damage.

C. The Federal Circuit's Opinion Is Contrary to the Plain Language of the Statute.

"As with any question of statutory interpretation, [the Court's] analysis begins with the plain language of the

statute." *Jimenez v. Quarterman*, 555 U.S. 113, 118 (2009) (citation omitted). It is well settled that when interpreting a statute, one must begin with "the assumption that the ordinary meaning of the language chosen by Congress accurately expresses the legislative purpose." *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 101 (2011) (internal quotation marks, modification, and citation omitted).

The ordinary meaning of § 102(a)(1) of the AIA requires that a sale of a claimed invention make the claimed invention "available to the public," in order for the sale to qualify as invalidating prior art. "Patented," "described in a printed publication," "public use," and "on sale" are all specific circumstances in which the claimed invention can be made available to the public. The catchall category "or otherwise available to the public," coming as it does at the end of the list of prior art categories, then references other ways in which the invention can be made "available to the public," and confirms that the terms preceding it—including the term "on sale"—also involve making the invention "available to the public."

Webster's Third New International Dictionary defines "otherwise" as "in a different way or another manner." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1598 (2002). In order for a claimed invention to become "available to the public" in a "different way or manner," there must be a referenced "way or manner" in which the invention is "available to the public."

In plain English, "or otherwise available to the public" means "or *in other ways* available to the public." The use of the "or otherwise" clause thus linguistically indicates that the "on sale" activity must make the claimed

invention "available to the public." This Court made a similar observation in *United States v. Standard Brewery, Inc.*, 251 U.S. 210, 217-18 (1920), disagreeing with the government's position that a statute prohibiting products for making "beer, wine, or other intoxicating malt or vinous liquor for beverage purposes" encompassed "beer and wine whether intoxicating or not," and concluding that the provision aimed "only at intoxicating beverages."

Any other interpretation of the statutory text would ignore or render superfluous the term "or otherwise," which would, in turn, violate "one of the most basic interpretive canons, that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (internal quotation marks, modification, and citation omitted). Indeed, this Court has long recognized that it is "not at liberty to construe any statute so as to deny effect to any part of its language." *Market Company v. Hoffman*, 101 U.S. 112, 115-16 (1879). The "or otherwise" language is in the statute for a reason. The *Helsinn* opinion effectively erases the "or otherwise" language from the statute.

Interpreting "on sale" to encompass secret sales would also be contrary to the most natural reading of the text. There is no dispute that the first three categories of prior art listed in § 102(a)(1)—inventions that are "patented," "described in printed publications," or "in public use"—are necessarily public. "In public use," and "on sale" both follow the ", or" that Congress added after "printed publication"—which deliberately set off the language: "or in public use, on sale or otherwise available to the public." Given that the penultimate category of prior art—

inventions that are "on sale"—is followed by the catchall category, "or otherwise available to the public," it stands to reason that, like the three preceding categories of prior art, and like the subsequent catchall category, sales also have to make the invention available to the public in order to qualify as potentially invalidating prior art. All five categories share the commonality of being "available to the public."

If Congress had wanted to exempt sales from the requirement that they be public to qualify as prior art, it could easily have drafted the statute so that it says so. For example, Congress could have placed the "otherwise available to the public" clause before "on sale" in the series, so that the section read: "[a] person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, in public use, or otherwise available to the public, or on sale, before the effective filing date of the claimed invention . . . ." Congress did not do so. The most natural and only reasonable interpretation of the language Congress actually chose is that the "claimed invention" that is "on sale" must be "available to the public" in order for the "sale" to be invalidating prior art. The term "otherwise" and the comma before the phrase "or otherwise available to the public" do not leave room for any other reasonable interpretation.

D. The Opinion Is Contrary to the Legislative History of § 102(a).

The House Committee Report accompanying the AIA could hardly be clearer that Congress intended to redefine the scope of invalidating prior art to exclude

art that was not publicly available: "[p]rior art will be measured from the filing date of the application and will typically include all art that *publicly exists* prior to the filing date, other than disclosures by the inventor within 1 year of filing." AIA Committee Report at 42 (emphasis added). The Report explains: "Thus, in section 102 the 'in this country' limitation as applied to 'public use' and 'on sale' is removed, and the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to *emphasize the fact that it must be publicly available.*" *Id.* at 42-43 (emphasis added); *see also* S. Rep. No. 111-18, 111th Cong., 1st Sess. at 6 (May 12, 2009).

The theme of public availability was reiterated by Senator Kyl on March 8, 2011, when he explained that Congress chose the word "otherwise" to "make[] clear that the preceding clauses describe things that are of the same quality or nature as the final clause—that is, although different categories of prior art are listed, all of them are limited to that which makes the invention 'available to the public.'" 157 Cong. Rec. S1368, S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (cited in final Committee Report, H.R. Rep. No. 112-98, at 43 n.20 (June 1, 2011)). In a hearing on the final bill on September 8, 2011, Senator Kyl again observed:

> As Chairman Smith most recently explained in his June 22 remarks, "contrary to current precedent, in order to trigger the bar in new 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date." . . . When the committee included the words "or otherwise available to the public" in section 102(a), the

> word "otherwise" made clear that the preceding items are things that are of the same quality or nature. As a result, the preceding events and things are limited to those that make the invention "available to the public."

157 Cong. Rec. S5431 (daily ed. September 8, 2011) (statement of Sen. Kyl) (quoting 157 Cong. Rec. H4429 (daily ed. June 22, 2011) (statement of Rep. Smith)).

A few years earlier, Senator Kyl explained that the purpose of "eliminating confidential sales and other secret activities as grounds for invalidity and imposing a general standard of public availability" was to "make the patent system simpler and more transparent," which change, in turn, will "provide greater certainty and predictability—it should also substantially reduce the need for discovery in patent litigation, since defendants will no longer need to uncover evidence of private sales or offers for sale or other nonpublic information in order to determine whether the patent is valid." 154 Cong. Rec. S9992 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl).

The Federal Circuit's suggestion that Congress either was not aware of how it was revising the scope of invalidating prior art, or was not aware of the consequences its changes would have, *Helsinn*, 855 F.3d at 1371, is untenable. Congress intended to revise the scope of invalidating prior art so that it did not encompass secret sales; the language it chose "accurately expresses [its] legislative purpose." *Microsoft*, 564 U.S. at 101.

E. The Opinion Is Contrary to the USPTO Interpretation and Guidelines.

Based on its review of the statutory text and the legislative history, the U.S. Patent Office concluded that the AIA requires that sales under § 102(a)(1) must be publicly available: "[t]he phrase 'on sale' in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA 35 U.S.C. 102(b), ***except that the sale must make the invention available to the public.***" Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11059, 11075 (Feb. 14, 2013) (emphasis added).

"These examination guidelines indicate that the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art ... [and] that an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if, for example, it is among individuals having an obligation of confidentiality to the inventor." *Id.* at 11060. The PTO explained that "[r]esidual clauses such as 'or otherwise' or 'or other' are generally viewed as modifying the preceding phrase or phrases," and that "[t]herefore, the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art." *Id.* at 11062 (citations omitted). It also noted "that the Office's interpretation is consistent with the interpretation that was clearly expressed by the bicameral sponsors of the AIA during the congressional deliberations on the measure." *Id.* (citations omitted).

The PTO also observed that some commentators said that "interpreting the 'on sale' provision to require public availability is good public policy in that it would lower litigation costs by simplifying discovery, and would reduce unexpected prior art pitfalls for inventors who are not well versed in the law." *Id.*

The PTO's interpretation not only is the most natural reading of the statute, but also reflects close attention to the statute's legislative history.

F. The Federal Circuit's Opinion Is Inconsistent with Established Canons of Statutory Construction.

1. Noscitur a Sociis: The "On Sale" Bar Reflects the "Company It Keeps."

Even if § 102 were ambiguous (which it is not), the "on sale" bar should be construed as requiring that an invalidating sale must be public. When a word or term of a statute is ambiguous or its meaning is doubtful, it may be interpreted in light of its associates, just like one "may know a person by the company he keeps." *Brown v. Chicago & N. W. R. Co.*, 77 N.W. 748, 752 (Wis. 1899).

The rule of noscitur a sociis (or the associated-words canon) "is a rule of construction to be applied where there is doubt and ambiguity concerning the meaning of a word or expression used by the legislative body in enacting a statute." *X-Acto Crescent Prods. Co., Inc. v. United States*, 27 Cust. Ct. 190, 192 (U.S. 1951); *see also Jarecki v. G. D. Searle & Co.*, 367 U.S. 303, 307 (1961) ("The maxim *noscitur a sociis*, that a word is known by the company

it keeps, while not an inescapable rule, is often wisely applied where a word is capable of many meanings in order to avoid the giving of unintended breadth to the Acts of Congress."); *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995); *Gutierrez v. Ada*, 528 U.S. 250, 255 (2000); *Yates v. United States*, 135 S. Ct. 1074, 1085 (2015).

For example, a statute saying "signed, or otherwise adopted or approved," was interpreted "by ordinary principles of noscitur a sociis" as meaning "an approval comparable to a signature." *United States v. Begaye*, 236 F.R.D. 448, 451 (D. Ariz. 2006) (discussing *Campbell v. United States*, 296 F.2d 527, 532-33 (1st Cir. 1961)). In *Jarecki*, this Court applied the maxim noscitur a sociis and said that in a statute having three words in conjunction—"exploration, discovery, or prospecting"—the word "discovery" "gathers meaning from the words around it," and because these words describe activity in the oil and gas and mining industries, "discovery" cannot be applied to development and manufacture of drugs and cameras. 367 U.S. at 307.

In accordance with the noscitur a sociis canon, the term "on sale" should be interpreted by association with both its closest neighbors ("in public use" and "otherwise available to the public") and its more distant neighbors ("patented" and "described in a printed publication"), all of which denote public availability.[11]

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11. Another related canon, the ejusdem generis rule (according to which, in a series of words of description, a general word can be limited to a meaning similar to that of objects of a like kind with the specified terms), further supports commonality of interpretation here. The U.S. Courts of Customs and Patent Appeals applied the ejusdem generis canon to hold that the

2. The "Last Antecedent" Canon Is Inapplicable.

The "last antecedent" doctrine, referenced in the concurring opinion in the Federal Circuit's order denying en banc review, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, No. 2016-1284, 2016-1787, slip op. at 7 (Fed. Cir. Jan. 16, 2018) ("Slip op."), is inapplicable here. The last antecedent rule "provides that 'a limiting clause or phrase . . . should ordinarily be read as modifying only the noun or phrase that it immediately follows'" and "reflects the basic intuition that when a modifier appears at the end of a list, it is easier to apply that modifier only to the item directly before it." *Lockhart v. United States*, 136 S. Ct. 958, 962-63 (2016) (quoting *Barnhart v. Thomas*, 540 U.S. 20, 46 (2003)).

The concurring opinion suggests that "the doctrine implies that 'to the public' limits only 'otherwise available.'" Slip op. at 7. Here, however, "otherwise" modifies "available to the public," not the other way around. Moreover, the "noun or phrase" immediately before "or otherwise available to the public" is "on sale."

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term "otherwise manufactured" in a provision stating that "[p]earl, mother of, and shells, not sawed, cut, flaked, polished, or otherwise manufactured" was to "take color and meaning from the enumerated operations, which are to be regarded as manufacturing operations within the purview" of this paragraph. *August Bentkamp v. United States*, 40 C.C.P.A. 70, 73, 77 (C.C.P.A. 1952). "To hold differently would be to ignore the plain meaning of the ... statutory language and *would in effect eliminate and render meaningless the word "otherwise"* in each of the[] paragraphs [at issue]. This is a result which we believe Congress clearly could not have intended." *Id.* at 77 (emphasis added).

If anything, application of the "last antecedent rule" would result in "otherwise available to the public" applying to "on sale."

The structure of § 102(a) does not invite application of the "last antecedent rule," because the type of "limiting clause or phrase" that calls for application of this doctrine is not present in the statute. Application of the canon also results in a cramped reading that is true neither to the provision's actual language nor to its legislative history. *Davis* v. *Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme").

The "last antecedent rule" simply is not a good linguistic fit here.

G. This Case Is an Ideal Vehicle for Addressing the Issue of Whether a Sale to a Third Party Subject to an Obligation to Keep the Invention Confidential Qualifies as Prior Art Under the AIA "On Sale Bar."

The scope of invalidating prior art is of critical importance in our patent system. The Court's intervention is required, at this time, to provide a definitive answer to the question at hand, so as to restore a measure of predictability and certainty in the U.S. patent system, and avoid countless unnecessary decisions and litigation interpreting and applying a wrong rule of law.

All participants in the patent system—inventors trying to develop their inventions and seeking partners to do so, companies deciding to enforce their own patents or to license or acquire patents from others, and investors valuing the patent portfolios of potential investment targets—must be able to determine what constitutes potentially invalidating prior art under the AIA, and what does not. The line between the two informs participants' decisions about how best to invest their resources, and whether or not to invest in innovation. Those decisions are based not only on their understanding of the law but also on their reliance on its stability. Uncertainty about the scope of invalidating prior art—and therefore about the scope of patent rights—benefits no one. It only decreases the patent system's ability to fulfill its purpose of fostering innovation and fueling economic growth.

This case presents an ideal vehicle for addressing the question of whether § 102(a) encompasses agreements where a third party is obligated to keep the invention confidential, because there are no factual disputes that could cloud the legal inquiry; the parties in this case do not dispute that the allegedly invalidating transactions at issue did not make the claimed invention itself publicly available. The question of whether such transactions constitute invalidating sales under the AIA is crucial for this Court to resolve at this time.

The Federal Circuit's *Helsinn* opinion indicates that its finding that the "on sale" bar applied was limited to the "particular Supply and Purchase Agreement" before it, but that finding necessarily turned on its conclusion that "if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms

of sale" in order for the "on sale" bar to apply. *Helsinn*, 855 F.3d at 1371. This broad construction of the "on sale" bar is directly contrary to the plain meaning of 35 U.S.C. § 102(a)(1), contrary to its purpose, contrary to its legislative history, and would defeat the efforts of the House and the Senate to harmonize the U.S. view of what counts as prior art with the views of the rest of the world. The "devil is in the details"—"prior art" cannot be invalidating prior art unless it makes the claimed invention available to the public. The Federal Circuit's characterization, its conclusion was not limited to the "particular Supply and Purchase Agreement" before it; rather, the court's conclusion necessarily turned on its holding that "if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale" in order for the "on sale" bar to apply. *Helsinn*, 855 F.3d at 1371. This approach is directly contrary to the plain meaning of 35 U.S.C. § 102(a)(1), contrary to its purpose, contrary to its legislative history, and would defeat the efforts of the House and the Senate to harmonize the U.S. view of what counts as prior art with the views of the rest of the world. The "devil is in the details"—"prior art" cannot be invalidating prior art unless it makes the claimed invention available to the public.

V. Conclusion

For the foregoing reasons, US Inventor respectfully requests that the Court grant Helsinn's petition for a writ of certiorari.

Respectfully submitted,

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April 2, 2018

No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

JOINT APPENDIX

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PETITION FOR A WRIT OF CERTIORARI FILED: FEBRUARY 28, 2018
CERTIORARI GRANTED: JUNE 25, 2018

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Helsinn press release, "Helsinn Healthcare Announce The Completion of Patient Enrollment for First Palonosetron Phase 3 Pivotal Trial" (Oct. 3, 2001) 407

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The following opinions, decisions, judgments, and orders have been omitted in printing the joint appendix because they appear as appendices to the petition for certiorari and the brief in opposition to the petition for certiorari as follows:

Br. in Opp. App. 1a:	Court of appeals order denying motion to stay mandate, Jan. 22, 2018
Pet. App. 1a:	Court of appeals order denying rehearing, Jan. 16, 2018
Pet. App. 17a:	Court of appeals opinion, May 1, 2017
Pet. App. 53a:	District court supplemental opinion, Mar. 3, 2016
Pet. App. 232a:	District court final judgment, Nov. 16, 2015
Pet. App. 235a:	District court memorandum opinion, Nov. 13, 2015

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

No. 16-1284

HELSINN HEALTHCARE S.A.,
Plaintiff-Appellee,

v.

TEVA PHARMACEUTICALS USA, INC.,
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Defendants-Appellants.

DOCKET ENTRIES

DATE	NO.	PROCEEDINGS
12/04/2015	1	Appeal docketed. Received: 12/03/2015. [293675] Entry of Appearance due 12/18/2015. Certificate of Interest is due on 12/18/2015. Docketing Statement due 12/18/2015. Appellant/Petitioner's brief is due 02/02/2016. [JCA] [Entered: 12/04/2015 01:12 PM]
* * * * *		
03/08/216	39	CORRECTED BRIEF FILED for Appellants Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. [38]. Number of

DATE	NO.	PROCEEDINGS
		Pages: 62. Service: 03/08/2016 by email. Pursuant to ECF-10, filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 03/14/2016. Appellees Helsinn Healthcare S.A. and Roche Palo Alto LLC brief is due 04/21/2016. [316820] [JCA] [Entered: 03/08/2016 03:50 PM]
		* * * * *
03/14/2016	43	AMICUS BRIEF FILED for 42 Intellectual Property Professors [42]. Number of Pages: 22. Service: 03/14/2016 by email. Pursuant to ECF-10, filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 03/21/2016. [318603] [JCA] [Entered: 03/15/2016 09:34 AM]
		* * * * *
03/15/2016	47	AMICUS BRIEF FILED for Ron D. Katznelson, Ph.D. [46]. Number of Pages: 27. Service: 03/15/2016 by clerk. [318912] [JCA] [Entered: 03/15/2016 04:11 PM]
		* * * * *
10/28/2015	59	AMICUS BRIEF FILED for Lamar Smith [56]. Number of Pages: 34. Service: 04/21/2016 by email.

DATE	NO.	PROCEEDINGS
		Pursuant to Fed. Cir. R. 29(a), filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 04/27/2016. [328738] [JCA] [Entered: 04/22/2016 10:08 AM]
		* * * * *
04/25/2016	64	BRIEF FILED for Appellees Helsinn Healthcare S.A. and Roche Palo Alto LLC [62]. Number of Pages: 60. Service: 04/25/2016 by email. Pursuant to Fed. Cir. R. 31(b), filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 05/02/2016. Appellants' reply brief due 5/13/2016. [329553] [MJL] [Entered: 04/26/2016 09:37 AM]
		* * * * *
04/27/2016	74	AMICUS BRIEF FILED for The Naples Roundtable, Inc. [67]. Number of Pages: 17. Service: 04/27/2016 by email. Pursuant to Fed. Cir. R. 29(a), filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 05/02/2016.

DATE	NO.	PROCEEDINGS
		[330068] [JCA] [Entered: 04/27/2016 03:20 PM]
05/02/2016	90	AMICUS BRIEF FILED for US [86]. Number of Pages: 25. Service: 05/02/2016 by email. Pursuant to Fed. Cir. R. 29(a), filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 05/09/2016. [331554] [JCA] [Entered: 05/03/2016 11:12 AM]
		* * * * *
05/02/2016	93	AMICUS BRIEF FILED for AIPLA [85]. Number of Pages: 26. Service: 05/02/2016 by email. Pursuant to Fed. Cir. R. 29(a), filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 05/09/2016. [331603] [JCA] [Entered: 05/03/2016 12:10 PM]
05/02/2016	97	AMICUS BRIEF FILED for Biotechnology Innovation Organization and Pharmaceutical Research and Manufacturers of America [89]. Number of Pages: 27. Service: 05/02/2016 by email. Pursuant to Fed. Cir. R. 29(a), filer is directed to file six copies of the brief in paper format. The paper copies of the

DATE	NO.	PROCEEDINGS
		brief should be received by the court on or before 05/09/2016. [331621] [JCA] [Entered: 05/03/2016 12:33 PM]
		* * * * *
05/13/2016	109	REPLY BRIEF FILED for Appellants Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. [108]. Number of Pages: 31. Service: 05/13/2016 by email. Pursuant to Fed. Cir. R. 31(b), filer is directed to file six copies of the brief in paper format. The paper copies of the brief should be received by the court on or before 05/23/2016. Appendix is due 05/23/2016. [335157] [JCA] [Entered: 05/16/2016 09:53 AM]
		* * * * *
05/23/2016	115	APPENDIX FILED for Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. [114]. Number of Pages: 624. Service: 05/23/2016 by email. Pursuant to Fed. Cir. R. 30(a)(5), filer is directed to file six copies of the appendix in paper format. The paper copies should be received by the court on or before 05/31/2016. [337793] [MJL] [Entered: 05/24/2016 09:40 AM]

DATE	NO.	PROCEEDINGS
		* * * * *
07/13/2016	123	Citation of Supplemental Authority pursuant to Fed. R. App. P. 28(j) for Appellants Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. Service: 07/13/2016 by email, US mail. [350548] [Andrew Nichols] [Entered: 07/13/2016 03:01 PM]
07/14/2016	124	Citation of Supplemental Authority pursuant to Fed. R. App. P. 28(j) for Appellee Helsinn Healthcare S.A. Service: 07/14/2016 by email. [350741] [Joseph O'Malley] [Entered: 07/14/2016 11:15 AM]
		* * * * *
10/04/2016	131	Submitted after ORAL ARGUMENT by Mr. William Ernest Havemann for US, Mr. George C. Lombardi, Esq. for Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. and Mr. Joseph M. O'Malley, Jr. for Helsinn Healthcare S.A. Panel: Judge: Dyk, Judge: Mayer, Judge: O'Malley. [371295] [JCP] [Entered: 10/04/2016 11:55 AM]
10/17/2016	132	Citation of Supplemental Authority pursuant to Fed. R. App. P. 28(j) for Appellee Helsinn Healthcare S.A. Service: 10/17/2016 by email, US

DATE	NO.	PROCEEDINGS
		mail. [374729] [Joseph O'Malley] [Entered: 10/17/2016 11:01 AM]
05/01/2017	133	OPINION and JUDGMENT filed. The judgment or decision is: Reversed. (Precedential Opinion). (For the Court: Dyk, Circuit Judge; Mayer, Circuit Judge and O'Malley, Circuit Judge). [428102] [16-1284, 16-1787] [JCA] [Entered: 05/01/2017 09:42 AM]
		* * * * *
06/30/2017	136	Petition for en banc rehearing filed by Appellee Helsinn Healthcare S.A. Service: 06/30/2017 by email, US mail. *The paper copies of the petition must be filed within two business days (see Fed. Cir. R. 35(c)(4).The required paper copies should be received by the court on or before 07/05/2017 [443615] [Joseph O'Malley] [Entered: 06/30/2017 03:57 PM]*
		* * * * *
07/11/2017	151	AMICUS BRIEF FILED on Petition for Lamar Smith [137]. Pages: 10. The filer is directed to submit the appropriate number of copies within two days, see Fed. Cir. R. 25(c). [445587] [SMJ] [Entered: 07/11/2017 12:01 PM]

DATE	NO.	PROCEEDINGS
		* * * * *
07/14/2017	157	AMICUS BRIEF FILED on Petition for Intellectual Property Owners Association [149]. Pages: 11. The filer is directed to submit the appropriate number of copies within two days, see Fed. Cir. R. 25(c). [446568] [SMJ] [Entered: 07/14/2017 10:53 AM]
		* * * * *
07/19/2017	177	AMICUS BRIEF FILED on Petition for AIPLA [156]. Pages: 10. The filer is directed to submit the appropriate number of copies within two days, see Fed. Cir. R. 25(c). [447619] [SMJ] [Entered: 07/19/2017 01:00 PM]
07/19/2017	178	AMICUS BRIEF FILED on Petition for Biotechnology Innovation Organization [160]. Pages: 10. The filer is directed to submit the appropriate number of copies within two days, see Fed. Cir. R. 25(c). [447621] [SMJ] [Entered: 07/19/2017 01:02 PM]
07/19/2017	179	AMICUS BRIEF FILED on Petition for Boston Patent Law Association [166]. Pages: 9. The filer is directed to submit the appropriate number of copies within two days, see Fed. Cir. R. 25(c). [447624]

DATE	NO.	PROCEEDINGS
		[SMJ] [Entered: 07/19/2017 01:10 PM]
07/19/2017	180	AMICUS BRIEF FILED on Petition for Pharmaceutical Research and Manufacturers of America [173]. Pages: 10. The filer is directed to submit the appropriate number of copies within two days, see Fed. Cir. R. 25(c). [447626] [SMJ] [Entered: 07/19/2017 01:15 PM]
* * * * *		
08/25/2017	193	RESPONSE of Appellants Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. to the petition for en banc rehearing [136] filed by Appellee Helsinn Healthcare S.A. in 16-1284. Service: 08/25/2017 by email, US mail. [456705] [Julia Johnson] [Entered: 08/25/2017 01:39 PM]
* * * * *		
01/16/2018	195	ORDER filed denying [136] petition for en banc rehearing filed by Helsinn Healthcare S.A. By: En Banc (Per Curiam). O'Malley, Circuit Judge, concurring in the denial of panel rehearing. Service as of this date by Clerk of Court. [489762] [SMJ] [Entered: 01/16/2018 02:01 PM]

DATE	NO.	PROCEEDINGS
		* * * * *
01/18/2018	199	MOTION of Appellee Helsinn Healthcare S.A. to stay execution of the mandate until Pending Petition for Writ of Certiorari. [Consent: opposed]. Service: 01/18/2018 by email, US mail. [490654] [Joseph O'Malley] [Entered: 01/18/2018 11:50 AM]
		* * * * *
01/22/2018	210	RESPONSE of Appellants Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. to the motion to stay mandate [199] filed by Appellee Helsinn Healthcare S.A. in 16-1284. Service: 01/22/2018 by email, US mail. [491404] [Steffen Johnson] [Entered: 01/22/2018 12:42 PM]
		* * * * *
01/22/2018	212	ORDER filed denying [199] motion to stay mandate filed by Helsinn Healthcare S.A. By: Merits Panel (Per Curiam). Service as of this date by Clerk of Court. [491632] [SMJ] [Entered: 01/22/2018 04:59 PM]
		* * * * *

DATE	NO.	PROCEEDINGS
01/29/2018	215	Mandate issued to the United States District Court for the District of New Jersey. Service as of this date by Clerk of Court. [493476] [16-1284, 16-1787] [SMJ] [Entered: 01/29/2018 04:32 PM]
03/05/2018	216	Petition for writ of Certiorari filed on 02/28/2018, and placed on the docket 03/02/2018, in the Supreme Court of the United States. Supreme Court #: 17-1229, Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., et al. [502582] [JAB] [Entered: 03/05/2018 02:54 PM]

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

No. 2:11-cv-03962-SRC-CLW

HELSINN HEALTHCARE S.A.,
Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC., and
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Defendants.

DOCKET ENTRIES

DATE	NO.	PROCEEDINGS
07/08/2011	1	COMPLAINT against DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SANDOZ INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC. (Filing fee $ 350 receipt number 3820157.) NO JURY DEMAND., filed by HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Civil Cover Sheet) (ma) (Entered: 07/11/2011)

DATE	NO.	PROCEEDINGS
		* * * * *
08/31/2011	33	ANSWER to Complaint, COUNTERCLAIM against All Plaintiffs by DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD. (Attachments: # 1 Certificate of Service) (IMBACUAN, MICHAEL) (Entered: 08/31/2011)
		* * * * *
09/13/2011	38	ANSWER to Complaint *For Patent Infringement*, COUNTERCLAIM against HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC by SANDOZ INC. (WIGGINS, SHEILA) (Entered: 09/13/2011)
09/13/2011	39	ANSWER to Complaint *and Affirmative Defenses* by TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC. (PATUNAS, MICHAEL) (Entered: 09/13/2011)
		* * * * *
10/05/2011	60	ANSWER to Counterclaim *of Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.* by HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC. (At-

DATE	NO.	PROCEEDINGS
		tachments: # 1 Certificate of Service) (LIZZA, CHARLES) (Entered: 10/05/2011)
		* * * * *
10/21/2011	67	ANSWER to Counterclaim *of Sandoz Inc.* by HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC. (Attachments: # 1 Certificate of Service) (LIZZA, CHARLES) (Entered: 10/21/2011)
		* * * * *
12/05/2011	77	ANSWER to Complaint by TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC. (PATUNAS, MICHAEL) (Entered: 12/05/2011)
		* * * * *
04/05/2012	85	STATEMENT *Joint Claim Construction and Prehearing Statement* by HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC. (Attachments: # 1 Certificate of Service) (LIZZA, CHARLES) (Entered: 04/05/2012)
		* * * * *

DATE	NO.	PROCEEDINGS
05/21/2012	88	BRIEF *Defendants' Opening Claim Construction Brief* (PATUNAS, MICHAEL) (Entered: 05/21/2012)
		* * * * *
05/21/2012	92	MARKMAN OPENING BRIEF *on behalf of Plaintiffs Helsinn Healthcare S.A. and Roche Palo Alto LLC* (Attachments: # 1 Declaration of A. Ni - Part 1, # 2 Declaration of A. Ni - Part 2, # 3 Certificate of Service) (LIZZA, CHARLES) (Entered: 05/21/2012)
		* * * * *
07/20/2012	94	MARKMAN RESPONSE BRIEF re 92 Markman Opening Brief (Attachments: # 1 Declaration of Julia Johnson) (PATUNAS, MICHAEL) (Entered: 07/20/2012)
		* * * * *
07/20/2012	96	MARKMAN RESPONSE BRIEF re 92 Markman Opening Brief (Attachments: # 1 Declaration of Angela C. Ni, # 2 Certificate of Service) (LIZZA, CHARLES) (Entered: 07/20/2012)
07/20/2012	97	MARKMAN RESPONSE BRIEF re 92 Markman Opening Brief (At-

DATE	NO.	PROCEEDINGS
		tachments: # 1 Declaration of Angela C. Ni) (LIZZA, CHARLES) (Entered: 07/20/2012)
		* * * * *
02/15/2013	124	MOTION to Amend/Correct *Invalidity Contentions* by TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC. (Attachments: # 1 Brief in Support of Motion for Leave to Amend Invalidity Contentions, # 2 Declaration of Mayra V. Tarantino, # 3 Exhibit 1, # 4 Exhibit 2, # 5 Exhibit 4, # 6 Exhibit 5, # 7 Exhibit 6, # 8 Exhibit 7, # 9 Exhibit 10, # 10 Exhibit 11, # 11 Exhibit 12, # 12 Text of Proposed Order) (TARANTINO, MAYRA) (Entered: 02/15/2013)
		* * * * *
03/08/2013	130	MEMORANDUM in Opposition filed by HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC re 124 MOTION to Amend/Correct *Invalidity Contentions*, 120 MOTION to Amend/Correct *Motion for Leave to Serve its Second Amended Invalidity Contentions*, 119 MOTION to Amend/Correct *Invalidity Contentions* (Attachments: # 1 Decla-

DATE	NO.	PROCEEDINGS
		ration of E. Dittmann, # 2 Certificate of Service) (LIZZA, CHARLES) (Entered: 03/08/2013)
		* * * * *
03/15/2013	134	REPLY BRIEF to Opposition to Motion filed by TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC. re 124 MOTION to Amend/Correct *Invalidity Contentions* (Attachments: # 1 Declaration of Mayra V. Tarantino, # 2 Exhibit C to Tarantino Declaration, # 3 Exhibit D to Tarantino Declaration, # 4 Exhibit E to Tarantino Declaration) (TARANTINO, MAYRA) (Entered: 03/15/2013)
		* * * * *
06/09/2014	175	STATEMENT *Joint Claim Construction and Prehearing Statement* by HELSINN HEALTHCARE S.A. (Attachments: # 1 Certificate of Service) (LIZZA, CHARLES) (Entered: 06/09/2014)
06/09/2014	176	MARKMAN OPENING BRIEF (Attachments: # 1 Declaration of Brendan F. Baker, # 2 Exhibit 1 to Declaration, # 3 Exhibit 2 to Decla-

DATE	NO.	PROCEEDINGS
		ration, # 4 Exhibit 3 to Declaration) (TARANTINO, MAYRA) (Entered: 06/19/2014)
06/19/2014	177	MARKMAN OPENING BRIEF OF PLAINTIFFS (LIZZA, CHARLES) (Entered: 06/19/2014)
		* * * * *
07/17/2014	181	MARKMAN RESPONSE BRIEF re 177 Markman Opening Brief, 176 Markman Opening Brief (Attachments: # 1 Declaration of Angela C. Ni, # 2 Certificate of Service) (LIZZA, CHARLES) (Entered: 07/17/2014)
07/17/2014	182	MARKMAN RESPONSE BRIEF re 177 Markman Opening Brief (Attachments: # 1 Declaration of Brendan F. Barker, # 2 Exhibit 1 to Declaration of Brendan F. Barker, # 3 Exhibit 2 to Declaration of Brendan F. Barker, # 4 Exhibit 3 to Declaration of Brendan F. Barker, # 5 Exhibit 4 to Declaration of Brendan F. Barker, # 6 Exhibit 5 to Declaration of Brendan F. Barker, # 7 Exhibit 6 to Declaration of Brendan F. Barker, # 8 Exhibit 7 to Declaration of Brendan F. Barker, # 9 Exhibit 8 to Declaration of Brendan F. Barker, # 10 Exhibit 9 to Declaration of Brendan

DATE	NO.	PROCEEDINGS
		F. Barker, # 11 Exhibit 10 to Declaration of Brendan F. Barker, # 12 Exhibit 11 to Declaration of Brendan F. Barker, # 13 Exhibit 12 to Declaration of Brendan F. Barker, # 14 Exhibit 13 to Declaration of Brendan F. Barker, # 15 Exhibit 14 to Declaration of Brendan F. Barker, # 16 Exhibit 15 to Declaration of Brendan F. Barker, # 17 Exhibit 16 to Declaration of Brendan F. Barker) (PATUNAS, MICHAEL) (Entered: 07/17/2014)
		* * * * *
09/05/2014	188	MOTION for Partial Summary Judgment *of Non Infringement of US Patent No. 8,598,219* by SANDOZ INC. (Attachments: # 1 Text of Proposed Order) (ABRAHAM, ERIC) (Entered: 09/05/2014)
09/05/2014	189	BRIEF *in Support of Motion for Partial SJ of Non Infringement of U.S. Patent No. 8,598,219* (ABRAHAM, ERIC) (Entered: 09/05/2014)
		* * * * *
09/05/2014	193	MOTION for Partial Summary Judgment *of Non-Infringement of U.S. Patent No. 8,598,219* by DR. REDDY'S LABORATORIES,

DATE	NO.	PROCEEDINGS
		INC., DR. REDDY'S LABORATORIES, LTD. (Attachments: # 1 Memorandum of Law, # 2 Imbacuan Declaration, # 3 Exhibits to Imbacuan Declaration, # 4 Rule 56.1 Statement, # 5 Text of Proposed Order, # 6 Certificate of Service) (IMBACUAN, MICHAEL) (Entered: 09/05/2014)
09/05/2014	194	MOTION for Summary Judgment *of Invalidity of US Patent 8,598,219* by SANDOZ INC. (Attachments: # 1 Text of Proposed Order) (ABRAHAM, ERIC) (Entered: 09/05/2014)
		* * * * *
09/05/2014	201	MOTION for Partial Summary Judgment *of Non-Infringement* by TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC. (Attachments: # 1 Declaration Brendan F. Barker, # 2 Exhibit 1, # 3 Exhibit 5, # 4 Text of Proposed Order) (TARANTINO, MAYRA) (Entered: 09/05/2014)
09/05/2014	202	MEMORANDUM in Support filed by TEVA PHARMACEUTICAL INDUSTRIES,LTD., TEVA PHARMACEUTICALS USA, INC. re 201 MOTION for Partial

DATE	NO.	PROCEEDINGS
		Summary Judgment *of Non-Infringement* (Attachments: # 1 Statement Pursuant to Rule 56.1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 6, # 6 Exhibit 7, # 7 Exhibit 8, # 8 Exhibit 9, # 9 Exhibit 10, # 10 Exhibit 11, # 11 Exhibit 12, # 12 Exhibit 13, # 13 Exhibit 14, # 14 Exhibit 15, # 15 Exhibit 16, # 16 Exhibit 17, # 17 Exhibit 18) (TARANTINO, MAYRA) (Entered: 09/05/2014)
		* * * * *
09/05/2014	204	BRIEF in Support filed by SANDOZ INC. re 194 MOTION for Summary Judgment *of Invalidity of US Patent 8,598,219* (ABRAHAM, ERIC) (Entered: 09/05/2014)
		* * * * *
09/05/2014	206	MOTION for Summary Judgment *of Infringement of U.S. Patent No. 8,598,219* by HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service) (LIZZA, CHARLES) (Entered: 09/05/2014)
09/05/2014	207	BRIEF *In Support of Plaintiffs' Motion for Summary Judgment of Infringement of U.S. Patent No.*

DATE	NO.	PROCEEDINGS
		8,598,219 (Attachments: # 1 Statement of Material Facts Not In Dispute, # 2 Declaration of D. Weir Part 1, # 3 Declaration of D. Weir Part 2, # 4 Declaration of D. Weir Part 3, # 5 Declaration of D. Weir Part 4, # 6 Declaration of D. Weir Part 5, # 7 Declaration of D. Weir Part 6) (LIZZA, CHARLES) (Entered: 09/05/2014)
09/05/2014	208	MOTION for Partial Summary Judgment *of No Invalidity* by HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC. (Attachments: # 1 Text of Proposed Order, # 2 Certificate of Service) (LIZZA, CHARLES) (Entered: 09/05/2014)
09/06/2014	209	BRIEF (Attachments: # 1 Statement of Material Facts Not in Dispute, # 2 Declaration, #3 Declaration, # 4 Declaration, # 5 Declaration, # 6 Declaration, # 7 Declaration, # 8 Declaration, # 9 Declaration, # 10 Declaration, # 11 Declaration, # 12 Declaration, # 13 Declaration, # 14 Declaration, # 15 Declaration, # 16 Declaration, # 17 Declaration) (LIZZA, CHARLES) (Entered: 09/06/2014)
* * * * *		

DATE	NO.	PROCEEDINGS
10/02/2014	219	BRIEF *in Support of Plaintiffs' Motion for Partial Summary Judgment of No Invalidity (Public Version)* (Attachments: # 1 Statement of Material Facts Not in Dispute (Public Version), # 2 Declaration of D. Weir - Part 1 (Public Version), # 3 Declaration of D. Weir - Part 2 (Public Version), # 4 Declaration of D. Weir - Part 3 (Public Version), # 5 Declaration of D. Weir - Part 4 (Public Version), # 6 Declaration of D. Weir - Part 5 (Public Version), # 7 Declaration of D. Weir - Part 6 (Public Version)) (LIZZA, CHARLES) (Entered: 10/02/2014)
		* * * * *
10/06/2014	221	RESPONSE in Opposition filed by DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD. re 206 MOTION for Summary Judgment *of Infringement of U.S. Patent No. 8,598,219* (Attachments: # 1 Declaration of Michael Imbacuan, # 2 Statement in Response to R. 56.1 Statement, # 3 Certificate of Service) (SENDER, STUART) (Entered: 10/06/2014)
		* * * * *

DATE	NO.	PROCEEDINGS
10/06/2014	225	BRIEF in Opposition filed by HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC re 193 MOTION for Partial Summary Judgment *of Non-Infringement of U.S. Patent No. 8,598,219*, 188 MOTION for Partial Summary Judgment *of Non Infringement of US Patent No. 8, 598,219*, 201 MOTION for Partial Summary Judgment *of Non-Infringement* (Attachments: # 1 Response to Teva's Rule 56.1 Statement, # 2 Response to DRL's Rule 56.1 Statement, # 3 Response to Sandoz's Rule 56.1 Statement, # 4 Declaration of D. Weir, # 5 Exhibit to D. Weir Declaration, # 6 Certificate of Service) (LIZZA, CHARLES) (Entered: 10/06/2014)
10/06/2014	226	BRIEF in Opposition filed by DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SANDOZ INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC. re 208 MOTION for Partial Summary Judgment *of No Invalidity* (Attachments: # 1 Certificate of Service) (ABRAHAM, ERIC) (Entered: 10/06/2014)

DATE	NO.	PROCEEDINGS
10/06/2014	227	BRIEF in Opposition filed by HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC re 194 MOTION for Summary Judgment *of Invalidity of US Patent 8,598,219* (Attachments: # 1 Response to Sandoz's Rule 56.1 Statement of Undisputed Facts, # 2 Declaration of J. Buckingham, # 3 Declaration of C. Peck - Part 1, # 4 Declaration of C. Peck - Part 2, # 5 Declaration of C. Peck - Part 3, # 6 Declaration of C. Peck - Part 4, # 7 Declaration of C. Peck - Part 5, # 8 Declaration of C. Peck - Part 6, # 9 Certificate of Service) LIZZA, CHARLES) (Entered: 10/06/2014)
		* * * * *
10/27/2014	230	REPLY to Response to Motion filed by DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD. re 193 MOTION for Partial Summary Judgment *of Non-Infringement of U.S. Patent No. 8,598,219* (Attachments: # 1 Certificate of Service) (SENDER, STUART) (Entered: 10/27/2014)
10/27/2014	231	REPLY BRIEF to Opposition to Motion filed by SANDOZ INC. re 194 MOTION for Summary Judgment *of Invalidity of US Patent*

DATE	NO.	PROCEEDINGS
		8,598,219 (Attachments: # 1 Certificate of Service) (ABRAHAM, ERIC) (Entered: 10/27/2014)
10/27/2014	232	REPLY BRIEF to Opposition to Motion filed by SANDOZ INC. re 188 MOTION for Partial Summary Judgment *of Non Infringement of US Patent No. 8, 598,219* (Attachments: # 1 Certificate of Service) ABRAHAM, ERIC) (Entered: 10/27/2014)
		* * * * *
10/27/2014	234	REPLY BRIEF to Opposition to Motion filed by TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC. re 201 MOTION for Partial Summary Judgment *of Non-Infringement* (Attachments: # 1 Declaration Cory Wohlbach, # 2 Exhibit Wohlbach Ex. A, # 3 Exhibit Wohlbach Ex. B, # 4 Exhibit Wohlbach Ex. C, # 5 Exhibit Wohlbach Ex. D, # 6 Exhibit Wohlbach Ex. E, # 7 Exhibit Wohlbach Ex. F, # 8 Exhibit Wohlbach Ex. H, # 9 Exhibit Barker Ex. 2, # 10 Exhibit Barker Ex. 4) (TARANTINO, MAYRA) (Entered: 10/27/2014)
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DATE	NO.	PROCEEDINGS
10/27/2014	236	REPLY BRIEF to Opposition to Motion filed by HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC re 208 MOTION for Partial Summary Judgment *of No Invalidity* (Attachments: # 1 Statement Response to Sandoz Inc.s Additional Statement of Material Facts in Support of Defendants Opposition to Plaintiffs Motion for Partial Summary Judgment of No Invalidity, # 2 Declaration of Steven Pollack, # 3 Exhibit 98-104 of Pollack Decl., # 4 Exhibit 105-106 of Pollack Decl., # 5 Exhibit 107-109 of Pollack Decl., # 6 Certificate of Service) (LIZZA, CHARLES) (Entered: 10/27/2014)
10/27/2014	237	REPLY BRIEF to Opposition to Motion filed by HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC re 206 MOTION for Summary Judgment *of Infringement of U.S. Patent No. 8,598,219* (Attachments: # 1 Declaration of Dana Weir, # 2 Certificate of Service) (LIZZA, CHARLES) (Entered: 10/27/2014)
* * * * *		
04/22/2015	290	MEMORANDUM OPINION filed. Signed by Judge Mary L. Cooper

DATE	NO.	PROCEEDINGS
		on 4/22/2015. (kas,) (Entered: 04/22/2015)
		* * * * *
05/19/2015	307	ORDER denying without prejudice 193 Motion for Partial Summary Judgment; denying without prejudice 201 Motion for Partial Summary Judgment; denying without prejudice 206 Motion for Summary Judgment ; denying without prejudice 208 Motion for Partial Summary Judgment. Signed by Judge Mary L. Cooper on 5/19/2015. (mmh) (Entered: 05/19/2015)
		* * * * *
05/21/2015	311	TRIAL BRIEF by HELSINN HEALTHCARE S.A., ROCHE PALO ALTO LLC. (Attachments: # 1 Certificate of Service) (LIZZA, CHARLES) (Entered: 05/21/2015)
05/21/2015	312	TRIAL BRIEF by TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC. (TARANTINO, MAYRA) (Entered: 05/21/2015)
		* * * * *
11/13/2015	360	MEMORANDUM OPINION. Signed by Judge Mary L. Cooper on 11/13/15. (eh,) (Entered: 11/16/2015)

DATE	NO.	PROCEEDINGS
11/16/2015	361	Letter from Helsinn to the Hon. Mary L. Cooper, U.S.D.J. (LIZZA, CHARLES) (Entered: 11/20/2015)
		* * * * *
03/03/2016	381	SUPPLEMENTAL OPINION. Signed by Judge Mary L. Cooper on 3/3/16. (eh,) (Entered: 03/03/2016)
		* * * * *
02/06/2018	401	ORDER & JUDGMENT VACATING THE FINAL JUDGMENT (DE No. 361) entered on November 16, 2015, including any and all relief under 35 U.S.C. § 271(e)(4)(A) and (B), thus permitting FDA to grant final approval to ANDA No. 090713. The order that the effective date of any final approval of ANDA No. 090713 shall be no earlier than July 30, 2024, is VACATED, etc. Signed by Judge Stanley R. Chesler on 2/6/18. (cm,) (Entered: 02/06/2018)

SUMMARY

Title of Study: A Dose-Ranging Efficacy, Safely, and Pharmacokinetic Study of Single Intravenous Doses of RS-26269 for Prevention of Nausea and Vomiting in Chemotherapy-Naive Cancer Patients Receiving Highly Emelogenic Chemotherapy

Study No. and RS No.: 2525952330 and RS-25259-197

Investigators and Study Centers: Multiple

Publications: None

Study Period: April 1994—April 1995

Clinical Phase: II

Objectives: The objectives of This study ware to (1) determine the dose-response relationship among single IV doses of RS-25259 over the dose range 1-90 ug/kg: the primary endpoint was the proportion of patients with a complete antiemetic response (no vomiting or retching) for 24 hours after highly emelogenic chemotherapy in chemotherapy-naive cancer patients; the efficacy of each dose was compared with the efficacy of the lowest dose; (2) assess the safety of single IV doses of RS-25259 administered over the range of doses tested in this patient population; and (3) assess the pharmacokinetics of single IV doses of RS-25259 over the range of doses lasted in This patient population.

Methodology: This was a randomized, double-blind, multicenter, dose-ranging efficacy, safety, and pharmacokinetic study of IV RS-25259-197. Patients were randomized to receive one of five doses of study drug and ware observed as Inpatients and/or outpatients. Safety and efficacy evaluations were recorded periodically during the first 24 hours and then daily for the

next 6 days following administration of study medication. Additionally, each patient was contacted 14 days postdosing to obtain further salary information. Blood samples for pharmacokinetic analysis were taken from patients at selected investigational sites before dosing and at various limes up to 168 hours after dosing with study drug; the plasma portion was assayed tor RS-25259 and RS-17825 (the N-oxide metabolite) concentrations, from which pharmacokinetics parameters were computed.

Number of Subjects: One hundred sixty-one patients (129 males. 32 females), 23-79 years of age were enrolled in this study. All patients are included in the safety evaluations. However, 13 patients were excluded from ail efficacy analysis. Reasons for exclusion included various protocol violations (8 patients). Subsequently to establishing evaluability, 5 additional patients, all of whom received cyclophosphamide, were also excluded. Thus, efficacy analyses focused on only patients who received cisplatin-based chemotherapy. The distribution of evaluable patients by dose group is as follows: 0.3-1 ug/kg, 29 patients; 3 ug/kg. 24 patients; 10 ug/kg. 25 patients; 30 ug/kg, 24 patients; and 90 ug/kg, 45 patients.

Diagnosis and Criteria for Inclusion: Patients were men and women who had histologically proven cancer, were chemotherapy naive, and were scheduled to receive their first dose of emelogenic chemotherapy, either cisplatin (> 70 mg/m2) or cyclophosphamide (> 1100 mg/m2).

Test Product Dose and Mode of Administration, Formulation No., Batch/Lot No.: RS-25259 was supplied in 5-mL glass vials at a concentration of 500 ug/mL, Patients were randomly assigned to one of five RS-25259 treatments. Prior to Amendments lit and IV of

the protocol, the treatments were 0.3,1, 3, 10, or 30 ug/kg; following those amendments, they were 1, 3, 10, 3e, or 90 ug/kg Normal saline was used to dilute RS-25259 to a total injection volume of 25 mL. Study drug was administered 30 minutes before start of chemotherapy and given as a single bolus IV dose over 30 seconds. The formulation number RS-25259 was No. F25259-006 (Lot Nos. 25259-197-12479 and 1021881),

Reference Therapy, Dose and Mode of Administration, Formulation No., Batch/Lot No.: None

Duration of Treatment: Patients received a single IV dose of RS-25269-197 over 30 seconds and wars subsequently followed for a total of 14 days.

Criteria for Evaluation: Clinical Data—The primary efficacy variable was the proportion of patients with a complete antiemetic response (no vomiting or retching, no rescue medication) for 24 hours after the start of chemotherapy. The efficacy of each dose was compared with the efficacy of the lowest dose. Secondary efficacy variables included the time to the first emetic episode, lime to administration of rescue therapy, area under the nausea-intensity-by-time (NIT) curve based on categorical scale, time to treatment failure (either emesis or need for rescue medication, whichever occurred first), proportion of patients with complete control of emesis (no vomiting and only mild nausea or no nausea), and global rating of satisfaction with the control of nausea and vomiting based on a visual analog scale. These variables were supplemented by physical examination and vital signs data, laboratory findings, and adverse event data. Pharmacokinetic Data—Plasma concentrations and computed Pharmacokinetic parameters for RS-25259 and RS-17825 were assessed.

Statistical Methods: Demographic and safety data were summarized; plasma concentrations and computed pharmacokinetic parameters were listed and statistically summarized by dose group; individual and mean plasma concentrations were plotted versus time; and computed parameters were analyzed for a dose relationship (e.g., close proportionality, dose linearly).

Summary and Conclusions: RS-25259, administered as a single bolus intravenous injection of 3, 10. 30 or 90 ug/kg 30 minutes prior to high-dose cisplatin chemotherapy, was effective in suppressing chemotherapy-induced emesis for 24 hours. All Four doses were approximately equally effective as compared with the combined results from a cohort of 0.3 and 1 ug/kg. The following table summarizes key efficacy parameters.

Parameters	RS-25259 Dose (ug/kg)				
	0.3-1	3	10	30	90
% Complete Control (24 hours)	24	46	40	50*	46
Complete Response (24 hours)	24	39	40	48	46
Median Time (hours) to Failure (first emetic episode or rescue Rx	5.6	22.7*	19.0	> 24*	21.8*

*statistically significant differences ($p < 0.05$) vs. lowest dose group

Safety evaluations and comparisons made between treatment groups all suggest that RS-25259 is a relatively safe therapeutic agent. No dose response-related adverse events were observed. One hundred twenty-nine of the 16 patients in the safety analyses (80.1%) experienced at least one adverse event during the study. A majority of events were rated as mild or moderate (469/559, 83.9%) and were considered probably not related to test medication (481/559. 86.0%). incidence, frequency, severity, and relationships of adverse events appeared to be essentially equally distributed among the RS-25259 treatment groups. The most frequent adverse event reported was headache, followed by constipation, pain, asthenia, anorexia, and diarrhea. Serious adverse events that occurred were all judged by the treating physicians to be probably not related to chemotherapy. No dose-related toxicity was observed in electrocardiograms or laboratory parameters evaluations.

Plasma AUC of RS-25259 Increased with increases in dose, and kinetics of RS-25259 were shown to be dose Proportional over the range of doses in this study (1-90 ug/kg) The mean observed T___ ranged from 8.6 to 49.6 minutes postdosing, although appreciable plasma concentrations of RS-25259, well above the limit of quantitation, were measured in the first sample drawn for nearly all patients at all dose levels. Mean C___ ranged from 0.880 to 336 ng/mL over the five dose levels. The mean half-life of RS-25259 ranged from 43.7 to 128 hours. Three patients had very long half-lives of 210, 246, and 383 hours. Mean values of clearance and volume al distribution ranged from 1.51 to 2.23 mL/min/kg and 6.83 to 12.5 L/kg respectively, over the five dose levels. There were no statistically significant differences in plasma concentrations or computed parameters over the range of doses studied.

Many pharmacokinetic parameters for RS-17825 could not be determined for the 1, 3, and 10 ug/kg dose levels because of very low plasma concentrations. For this reason, dose proportionality could not be determined for RS-17825. The mean T___ of RS-17825 ranged from 0.208 to 112 hours and the mean

ranged from 0.0549 to 0.855 ng/mL across the live dose levels. The mean half-ere of RS-17826 averaged 59.1 and 110 hours at the two top dose levels for which it could be calculated (30 and 90 ug/kg). Several patients had long RS-17826 half-lives ranging from 106 to 434 hours. Across all five dose levels, C___ and T___ showed statistically significant differences, but $AUC_{0\text{-}24}$, did not. Hall-life and total AUC were not statistically different across the two top dose levels for which they could be calculated_ The mean AUC ratio of RS-17825 to RS-25259 total AUG averaged 4.1178 and 0.0789 and indicated a small presence in plasma of the N-cxide metabolite relative to the RS-25259 parent compound.

Based on the results of this study, a dose of 3 ug/kg or 10 ug/kg RS-25259 might be appropriate for further development. Pharmacokinetically, RS-25259 demonstrated dose-proportional kinetics with no statistically significant differences in parameters across the five dose levels. The plasma half-life was exceptionally long for this class of compound, arid a few patients demonstrated very long half-lives compared with the other patients. Human exposure to the N-oxide metabolite (RS-17825) in the plasma was minor relative to the parent compound.

/s/ Wolfgang B. Strauss, B.Sc. Sept 25, 95

Wolfgang B. Strauss, B.Sc. Date

Center for Clinical Research Physicians

/s/ Daniel L. Combs, B.S. — Sept 25, 95
Daniel L. Combs, B.S. — Date
Center for Clinical Pharmacology
and Clinical Pharmacokinetics

/s/ Gil Fine — Sept 25, 95
Gil Fine, Ph.D. — Date
Center for Biometrics and
Database Management

Confidential

Meeting Minutes

re	Helsinn Palonosetron Team Meetings
Location	3S5 Sherman Ave., Suite 5, Palo Alto, CA 94306
Date and time	Monday July 20, 1998 – Friday July 24, 1998
Attendees	Monday July 20 attendees Mr. Dario Ceriani, Alberto Macciocchi, M.D., Bob Hill Ph.D., and Martha A. Reitman M.D.

Tuesday July 21 attendees Mr. Dario Ceriani. Alberto Macciocchi, MD., Martha A. Reitman M.D., [Alan Krubiner Ph.D., attorney (lunch meeting)]

Wednesday July 22 attendees Mr. Dario Ceriani, Alberto Macciocchi, MD., Martha A. Reitman M.D, Dr. Giorgio Calderari, Dr. Ron Pearl, Mr. Bob Ignaffo

Thursday July 23, Friday July 24 attendees Mr. Dario Ceriani, Alberto Macciocchi, M.D., Martha A. Reitman M.D. Dr. Giorgio Calderari, Tom Malcfyt, PhD., Chandu Hegde, Maryann Lee, Li-Hwa Lin, Don Curley, Hans Schmid (part-time)

Thursday July 23, Alberto Macciocchi, M.D., Dr. David Gandarra (University of California, Davis)

Thursday July 23 Roche-Syntex Lunch attendees Mr. Dario Ceriani, Martha A. Reitman M.D, Dr. Giorgio Calderari, Dr. Sharyn Solish, Mr. Wolff Strauss, Ms. Anne Hopkins, Mr. Bruce Kowalczek, Dr. Tom Malefyt, Dr. Pity Penumarthy. Ms. Barbara Simkin

Friday, July 24 attendees Mr. Dario Ceriani, Alberto Macciocchi, M.D., Martha A. Reitman M.D, Dr. Giorgio Caiderari, Ms. Gayle Mills, Ms. Anne Hopkins

CINE study designs There are two ways to set up the high dose trial. Comparison of all groups with the low dose of Palo, or comparison between each dose and ondansetron.

The low dose should not be too low (not ethical). The proposal is to test effective doses seen in Phase 2 (3. 10, and 30 ug/kg) compared to ondansetron 32 mg.

0.25, 0.75 and 2 mg are she three proposed doses (to be confirmed by the phase 2 analyses outlined above). The volume is planned to be 5 ml.

The definitions of CR (no emesis, no rescue medication) and CC (no nausea, no emesis, no rescue medication) were confirmed. CC at 24 hours will be the primary efficacy endpoint. Continued control beyond 24 hours will be a secondary endpoint. Missing data will be counted as a treatment failure.

The management of dexamethasone in the trial and the evaluation of repeat cycles will need further discussion.

PONV 1. Ina review of 2500, the median time to first emesis was evaluated (it is long for placebo and the treatment groups). It was determined that this was without regard to the use of rescue medication, and a review of complete responders (table 16A and figure 5) was more in keeping with Dr. Pearl's experience.

2. The dose which provides efficacy is L ug/kg, with the possibility that 3 ug/kg is more effective. The trial will include both doses. Doses planned include 0.1 mg and 0.3 mg (in 2 m1).

3. An analysis by sex and ug/kg converted to mg is planned to confirm these doses.

4. A review of dolasetron and ondansetron demonstrated that that multiple doses were assessed in phase 3. For dolasetron PONV prophylaxis, three trials were conducted (N on treatment = approximately L600) and for PONV treatment, two trials were conducted (N on treatment= approximately 800). It needs to be determined whether a program for prophylaxis only would be acceptable to FDA.

Continued on next page

A Double-Blind Clinical Study to Compare Single IV Doses of Palonosetron, 0.25 mg or 0.75 mg, and Ondansetron, 32 mg IV, in the Prevention of Moderately Emetogenic Chemotherapy-Induced Nausea and Vomiting

Protocol No. PALO-99-03

Sponsor:
Helsinn Healthcare SA
P.O. Box 357
5915 Pambio-Noranco (Lugano)
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Telephone: (091) 985 21 21
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Protocol Date: 15 November 1999

Confidential Information

The information contained in this document is confidential. Acceptance of this document constitutes agreement by the recipient that no information contained herein will be published or disclosed without prior written authorization front an official of Helsinn Healthcare SA, except that this document may be disclosed to appropriate Institutional Review I Boards

and Ethics Committees or duly authorized representatives of a national regulatory authority under the condition that they are requested to keep it confidential:

1.0 INTRODUCTION

1.1. Background and Rationale

Nausea and vomiting are among the most unpleasant and distressing subjective side effects of cancer chemotherapy (1,2). Chemotherapy-induced nausea and vomiting (CINV) reduces a patient's quality of life (3) and may cause non-compliance or refusal of potential life-saving chemotherapeutic regimens (2). Although the severity and pattern of nausea and vomiting induced by a chemotherapeutic regimen depend on the agents used and the doses employed (4), The neuropharmacology of highly or moderately emetogenic CINV is similar (5).

Research into preventing CINV has been directed at blocking receptors for neurotransmitters, such as dopamine, 5-hydroxytryptamine (5-HT, scrotonin), endorphin, and substance P, which are found in the brainstem vomiting center. The initial clinical research was focused on blocking dopamine receptors with metoclopramide, phenothiazines and butyrophenones (6). Metoclopramide was later found to bind with the 5-HT receptor (6). Data indicating that nausea and vomiting may be triggered by the release of 5-HT involving both the gastrointestinal tract and the central nervous system lead to the important discovery of the selective 5-HT, receptor antagonists; ondansetron. granisetron, and dolasetron (7). These agents have demonstrated greater selective antiemetic effects than high doses of metoclopramide (8-10). In addition, 5-HT, receptor antagonists have been well tolerated and free of extrapyramidal toxicity

which is occasionally reported with agents which block dopamine transmission. When administered alone (9-12) or in combination with dexamethasone (13-15), 5-HT, receptor antagonists offer better anti-emetic control of CINV than other presently marketed classes of anti-emetics.

Palonosetron is a novel, potent, and selective 5-HT receptor antagonist. It has been evaluated as an anti-emetic for use in CINV and postoperative nausea and vomiting (PONV). In animal models of chemotherapy-induced emesis, palonosetron completely inhibits emesis in up to 100% of animals given high-dose cisplatin (16). In healthy, adult volunteers, the mean half-life of palonosetron, administered either IV or orally, is approximately 4.0 hours, which is 4 to 10 times longer than the currently marketed 5-HT, receptor antagonists [4 hours for ondansetron (17), 9 hours fur granisetron (18), and approximately 7 hours for the active metabolite of dolasetron (19)]. Results achieved in Phase H CINV studies suggest that palonosetron is safe and effective in preventing nausea and vomiting following emetogenic chemotherapy, especially during the first 24 hours after administration (16).

Given the high affinity of palonosetron for the 5-HT, receptor and efficacy results in both animal models and in Phase II studies, a single dose of palonosetron is expected to control acute CINV following moderately and highly emetogenic chemotherapy. Furthermore, due to the long half-life of palonosetron in humans, a single dose of palonosetron may also be beneficial in controlling the delayed phase (24-120 hours) of nausea and vomiting induced by a chemotherapeutic regimen. This study is designed to support the hypotheses that palonosetron is nor inferior to

currently available 5-HT, receptor antagonists and is effective in preventing nausea and vomiting following moderately emetogenic chemotherapy, regardless of the chemotherapy regimen. In this study, the active comparator chosen is odansetron, which is a selective 5-HT, receptor antagonist widely used in the prevention of MTV (10-14, 17, also see Appendix H).

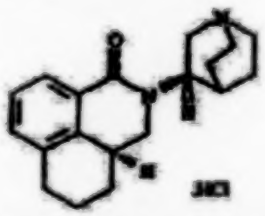
Based on the Phase II data (see Section 1.43), fixed doses of palonosetron. 025 mg (3 ug/kg) and 0.75 mg (10 ug/kg) were chosen as the optimal doses for the Phase ID trials.

1.2. Chemical and Pharmaceutical Properties of Palonosetron

1.2.1. Chemical Name an International Non-Proprietary Name (INN)

- (3aS-2-[(S)-I-Azabicyclo[2.2.2]oct-3-yl)-2,3,3a,4,5,6-hexahydro-1-oxo-1H-benx[de]isoquinoline hydrochloride
- Palonosetron hydrochloride

1.2.2. Chemical Structure



Palonosetron hydrochloride

Palonosetron is structurally unrelated to currently available 5-HT, receptor antagonists.

1.2.3. Pharmaceutical Formulations and Storage and Handling of Study Drug

The formulations to be used for the Phase DI clinical studies are sterile, isotonic, buffered solutions for IV administration alone or as an admixture with isotonic saline. The injectable solutions should be stored at room temperature and protected from exposure to direct light. Solutions that have inadvertently become frozen should not be used, but should be returned to the sponsor for disposal and replacement.

1.3. Preclinical Studies

Extensive *in vitro* and *in vivo* pharmacologic studies for palonosetron have been conducted. The key information from these studies are:

- Palonosetron has high affinity and specificity for 5-HT, receptors.

and/or solicited adverse event. Each subject received a single dose of palonosetron HCl or placebo. Individual doses were based on body weight. The doses ranged from 0.3-90 ug/kg for the IV studies, and from 3-80 ug/kg for the oral studies.

Phase I studies have characterized the safety and pharmacokinetics of palonosetron given IV and orally. The data indicate the following:

- Palonosetron was well tolerated up to doses of 90 ug/kg.
- There were no significant ECG abnormalities except one subject with brief asymptomatic episodes of second-degree A-V block and one episode of sinus exit block.
- Most frequent adverse events were headache, constipation, abdominal pain, and transiently elevated liver enzymes which did not appear dose-related. Adverse events were generally mild to moderate.

1.4.2. Human Pharrnacokinetics

The mean maximum plasma concentration (C___) and area under the concentration-time curve (AUC) were generally proportional to dose after IV and after oral dosing in healthy subjects, as well as postoperative and cancer patients. The mean time to maximum plasma concentration (T___) after oral administration was generally 4-6 hours. The mean plasma elimination half-life (T___) was approximately 40 hours in subjects given single IV or oral doses. Approximately 50% of palonosetron is metabolized and about 40% is renally cleared unchanged. The major metabolite found in plasma is the N-oxide metabolite (Metabolite 9). in virro studies using human plasma have shown that palonosetron hydrochloride is 62% plasma-protein bound over the range of concentrations (5-412 ng/mL).

1.4.3. Phase II Studies

Several Phase II studies have been conducted to evaluate safety and efficacy of palonosetron HCl including one clinical trial (study 2330) of intravenous palonosetron Ha and one oral study (study 2332) in the prevention of highly emetogenic CINV. There were two additional clinical trials conducted for post-operative nausea and vomiting run concurrently with the CINV program: one utilized intravenous and one utilized oral administration (2500 and 2502, respectively). Data from studies 2332, 2500 and 2502 contribute to an understanding of the overall safety profile of palonosetron HCl.

Study 2330 was a randomized, double-blind, multicenter, dose-ranging design. It evaluated the efficacy, safety, and pharmacokinetics of single intravenous doses of palonosetron HCl for the prevention of nausea

and vomiting in patients receiving highly emetogenic chemotherapy. All patients were chemotherapy naive, had histologically-proven cancer and received either cisplatin (>70 mg/m2) or cyclophosphamide (>1100 mg/m2). Thirty minutes before administration of the chemotherapeutic agent(s), study drug was administered by IV bolus over 30 seconds. The original protocol called for patients to receive one of five IV doses of palonosetron (0.3, I, 3, 10, or 30 ug/kg). Based on the early blinded data from a limited number of patients the protocol was amended to discontinue the lowest dose (0.3 ug/kg) and to add a higher dose (90 ug/kg) for a new treatment. The 03 ug/kg patients were merged with the 1 ug/kg patients to form a 0.3-1 ug/kg group.

One hundred sixty one patients (129 males, 32 females), 23-79 years of age were enrolled in this study to obtain 148 evaluable patients. All evaluable patients received cisplatin-based chemotherapy. The distribution of evaluable patients by dose group was as follows: 0.3-1 ug/kg palonosetron, 29 patients; 3 ug/kg, 24 patients; 10 ug/kg, 25 patients; 30 ug/kg, 24 patients: and 90 ug/kg, 46 patients. Patients were evaluated periodically during the first 24 hours following administration of chemotherapy then daily for 7 days and again at 14 days post chemotherapy fora final safety review.

The primary efficacy variable was the proportion of patients with a complete anti-emetic response (CR, no vomiting or retching and no rescue medication) for 24 hours after the start of chemotherapy. The efficacy of each dose was compared with the efficacy of the lowest dose. Secondary efficacy variables included the time to the first emetic episode, time to rescue therapy, area under the nausea intensity-by-time (NTT) curve based on categorical scale, time to treatment failure (either

emesis or administration of rescue medication, whichever occurred first), proportion of patients with complete control of emesis (CC, no emetic episodes, only mild nausea or no nausea and no rescue medication for 24 hours after the start of chemotherapy), and global rating of satisfaction with the control of nausea and vomiting. These variables were supplemented by physical examination and vital signs data, laboratory findings, ECGs, and adverse event data.

The following table summarizes the results for the following parameters:

a) Complete response (CR)

b) Complete control (CC)

c) Median time to failure

Study 2330

Summary of Patients' Responses for 24 Hours After Chemotherapy (Evaluable Patients)

	0.3-1 ug/kg	3 ug/kg	10 ug/kg	30 ug/kg	90 ug/kg
n	29	24	25	24	46
% with CR	24%	46%	40%	50%	46%
p-Value[a]	–	0.103	0.079	0.047	0.128
n	29	23	25	23	46
% with CC	24%	39%	40%	48%	46%
p-Value[a]	–	0.178	0.079	0.079	0.128
n	29	24	25	24	46
Time to Failure (hr) (median)	5.6	22.7	19.0	> 24	21.8
p-Value[a]	–	0.011	0.098	0.010	0.004

*p-value for comparison with low-doses (0.3-1 ug/kg) treatment group

Data from this study clearly demonstrate that the 3 ug/kg dose of palonosetron is the minimal effective dose in preventing CINV. The results of this study also suggest that palonosetron is a well tolerated compound. Although 129 (80.1%) patients experienced at least one adverse event during the study (14 days of observation), the majority of events (83.9%) were rated as mild or moderate and relationship to test medication was usually considered "probably not related" (86.0%). Adverse events were essentially equally distributed across the various dose groups and no dose response effects are apparent. Evaluations of ECGs and laboratory parameters were uneventful, confirming palonosetron tolerance.

The most frequently reported adverse events, occurring in 5% or more of the total number of patients who received palonosetron in the Phase I and Phase II studies, were: headache, constipation, fever, abdominal pain, diarrhea, itching (pruritus), pain, asthenia, and insomnia. In addition, dizziness and anorexia were reported in more than 5% of the patients who received > 30 ug/kg of palonosetron, and back pain was reported in more than 5% of the patients who received 10-20 ug/kg of palonosetron. Instances of an increase in liver enzymes, tachycardia, bradycardia, abnormal electrocardiograms, chest pain (angina), hypotension, and hypertension have also been mooned.

For further information about palonosetron, please refer to the Investigator's Brochure 06).

2.0 OBJECTIVES OF THE STUDY

2.1. Primary

- To compare the efftcacy of single IV doses of palonosetron, 0.25 mg or 0.75 mg, to ondansetron 32 mg IV in preventing moderately emetogenic CINV.

2.2. Secondary

- To evaluate the safety and tolerability of palonosetron and its relative safety in comparison with ondansetron.
- To evaluate the effect of anti-emetic control with palonosetron or ondansetron on the quality of life of patients receiving moderately emetogenic chemotherapy.

3.0 STUDY DESIGN

This is a multicenter, Phase III, randomized, balanced, controlled, double-blind, double-dummy, parallel, stratified, and active comparator study design comparing the efficacy, safety and tolerability of single IV doses of palonosetron, 0.25 mg or 0.75 mg, with a single IV dose of ondansetron 32 mg, in the prevention of moderately emetogenic WV. The active comparator, ondansetron 32 mg, is the U.S. FDA-approved IV regimen for the prevention of nausea and vomiting following moderately emetogenic chemotherapy. This dose is also normally used in Europe for the prevention of CAN. Implementation of published historical placebo controls will be used to validate the trial, demonstrating its sensitivity. It is

Helsinn Announces That Patient Enrollment For Phase III Palonosetron Trials Progresses Both in the USA and Europe.

Date: Sep 14, 2000

Words: 367

Publication: PR Newswire

LUGANO, Switzerland, Sept. 14 /PRNewswire/ –

Helsinn Healthcare SA announced today that the enrollment of the patients for Phase III clinical trials is progressing as scheduled. The patients are treated with Palonosetron, a novel treatment for the prevention of chemotherapy induced nausea and vomiting. Palonosetron is expected to provide an extended antiemetic coverage to cancer patients versus the existing 5-HT3 receptor antagonists thus reducing the need of multiple administrations.

The company will enroll over 1,800 patients in multicenter, randomized, balanced, controlled, double-blind, stratified, parallel and active comparator design studies. The Phase III efficacy protocols have been approved by the FDA according to the Modernization Act procedures (FDAMA). The trials will be conducted in about 80 already active centers across North America (40 centers) and Europe (40 centers).

"The Phase 11 trials demonstrated the efficacy of Palonosetron in the prevention of emesis with no significant side effects on the cardiovascular, respiratory, gastrointestinal, CNS and renal systems," said Luigi Baroni M.D., Director of Scientific Affairs. "We are now eager to complete the data necessary for the NDA filing scheduled for early 2002."

Additionally, both the technology transfer of the Palonosetron synthesis process from the originator's

plant and the development of the i.v. finished dosage form have been succesfully accomplished.

"I am pleased to see the completion of the production of the first batch of Palonosetron active ingredient at Helsinn's new state-of-the-art facility (Helsinn Advanced Synthesis SA) dedicated to the production of high-potency active ingredients. Upon market approval, Helsinn will be in the position to supply its marketing partners with a finished product ready for distribution," said Giorgio Calderari, Director, Technical Affairs.

Helsinn is seeking marketing partners for this patented product in different territories.

Helsinn is a privately owned pharmaceutical group with headquarters in Switzerland. Helsinn's core business is licensing. The company's business strategy is to in-license new chemical entities at a certain stage of development. Helsinn completes the development by performing pre-clinical and clinical studies as well as chemical and pharmaceutical development through the attainment of market approval in strategic markets (USA and Europe). The finished products are manufactured at Helsinn and out-licensed to its marketing partners for distribution.

Additional information is available at www.helsinn.com.

License Agreement

between

HELSINN HEALTHCARE SA

and

MGI PHARMA, INC.

for

PALONOSETRON

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THIS AGREEMENT (hereinafter called "Agreement") is effective as of this 6th day of April 2001 (hereinafter called "Effective Date), between HELSINN HEALTHCARE SA, a corporation organized and existing under the law of Switzerland and having its registered office at Via Pian Scairolo, 6912 Pazzallo, Switzerland (hereinafter called "HHC") of the one part, and MGI PHARMA, INC., a corporation organized and existing under the law of the state of Minnesota, United States of America and having its registered office at 6300 West Old Shakopee Road, Suite 110, Bloomington, MN 55438-2318, USA (hereinafter called "MGI"), of the other part.

RECITALS

a. HHC carries on business as a licensing company, product developer and pharmaceutical trader and, in particular for the purpose of this Agreement, has inlicensed from the companies Syntex (U.S.A.) Inc. and F. Hoffmann-La Roche AG by means of a License Agreement dated June 23, 1998 (hereinafter, the "Syntex Agreement") world-wide exclusive rights to certain patents and know-how to make, have made, develop, register, market, distribute and sell, directly or indirectly, the Compound (as hereinafter defined) and pharmaceutical preparations containing said Compound as active pharmaceutical ingredient.

b. MGI carries on business as a pharmaceutical company and, in particular for the purpose of this Agreement, represents that it is a reputable pharmaceutical company, having a size and a position on the market adequate to effectively market, distribute and sell the Products (as hereinafter defined) and that it has the necessary sales force to successfully sell the Products in the Field throughout the Territory (as hereinafter defined).

c. Prior to entering into discussions with HHC, MGI possessed no technology and limited information of its own (including publicly available information) relating to the Compound and/or the Products. The Parties entered on 25th May 2000 into a Secrecy Agreement by means of which HHC disclosed to MGI confidential information and data relating to the Compound and Products.

d. The Parties entered on October 5th 2000 into a Letter of Intent on which basis they have performed respective appropriate due diligence for the purpose of establishing their interest and willingness to enter into this Agreement, and hereby confirm that (i) each has been provided with full and complete access to such information as they deemed necessary or appropriate to conduct due diligence, and (ii) such due diligence has been completed to their full satisfaction.

e. MGI now wishes to acquire the right to act as HHC's licensee and distributor for the Products in the Territory and HHC is willing to so appoint MGI under the terms and conditions hereinafter set forth.

f. The Parties agree that this preamble constitutes an integral part of this Agreement and all capitalized terms used in this preamble shall have the meaning as defined in Article I hereafter.

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants and conditions herein contained, the Parties hereby agree as follows:

ARTICLE 1 - DEFINITIONS

The following terms as used in this Agreement have, unless the context clearly indicates otherwise, the following meanings:

1.1 "Accounting Period" means the quarters ending 31st March, 30th June, 30th September and 31st December in each year throughout the term of this Agreement.

1.2 "Affiliate" means an organization that, whether now or in the future, controls, is controlled by or is under common control with a Party. For the purposes of this definition, the terms "controls," "controlled by," and "under common control with" as used with respect to any Party, means the. possession (directly or indirectly) of fifty percent or more of the voting stock or other equity interest of a subject entity with the power to vote, or the power in fact to control the management decisions of such entity through the ownership of securities or by contract or otherwise.

1.3 "Compound" means the active pharmaceutical ingredient (3aS-2-[(S)-1-Azabicyclo[2.2.2]oct.-3-yl]-2,3,3a,4,5,6-hexahydro-1-oxo-1H-benz[de]isoquinoline hydrochloride, having the generic name palonosetron hydrochloride (INN) for use in human medicine.

1.4 "FDA" means the U.S. Food and Drug Administration or any successor agency.

1.5 "Field" means the prevention of chemotherapy induced nausea and vomiting (CINV) in terms of the Regulatory Authorities approved indication.

1.6 "HHC's Other Distributors" means any distributor and/or licensee appointed by HHC to promote and sell pharmaceutical preparations containing the Compound in any country of the world outside the Territory and outside the Field in the Territory.

1.7 "Improvements" means all improvements, modifications or developments relating to the Field and/or to the Product forms subject of this Agreement, which

might improve the quality or improve consumer acceptance and/or patient compliance of the Products. For clarity, except to the extent MGI has exercised its right of first refusal wider Article 2.6, "Improvements shall not include dosage forms other than the intravenous ("I.V.") formulation as shall be described in the Registration and/or indications other than within the Field.

1.8 "Know-how" means valuable, secret and substantial information regarding the Products in the Field, including but not limited to documentation and information on file with the FDA or other Regulatory Authority in support of the Registration, which may be necessary, useful or advisable to enable MGI to promote, market and sell the Products in the Field in the Territory, as far as controlled by or available to, and not prohibited to be disclosed or licensed by, HHC, all as listed in the First Appendix hereto and as is or will be specified in the documentation which HHC has delivered or will deliver to MGI after execution of this Agreement.

1.9 "Net Sales" means the gross sales in local currencies of all Products said in the Territory by MGI and/or its Affiliates, including any local Affiliate in Canada, for arm's lenghth sales to any non-Affiliated third party less those normal and customary deductions made under Generally Accepted Accounting Principles to are at Product sales. Such deductions shall comprise any trade and quantity discounts, returns and allowances, rebates, cash discounts, sales and excise taxes, transportation and insurance charges, chargebacks and other amounts paid on sale or distribution of Product, provided that such deductions (i) arc directly linked to and related to the gross sales

invoiced amount, (ii) are specifically related to commercial policies having the purpose of acquiring, maintaining and maximising sales and enlarging the market share of the Product, (iii) do not exceed the average usual and customary deductions of this kind for similar products in the Field in the Territory and (iv) shall not include any mark-up or other increase over costs actually incurred by MGI and/or its Affiliates in connection with such gross sales. It is understood that said deductions shall not include any amount related to had or doubtful debts. Where (a) a Product is sold as one of a number of items (bundled transaction) without a separate price; or (h) the consideration for the Product shall include any non-cash element; or (c) the Product shall be transferred in any manner other than an invoiced sale, the Net Sales applicable to the quantity of Product of any such transaction shall be deemed to be the average Net Sales for all other transactions of Product at that time in the Territory.

1.10 "Parties" means HHC and MGI and "Party" means either of them as the context indicates.

1.11 "Patent" means (a) the patents and the patent applications licensed or assigned to HHC pursuant to the Syntex Agreement, as listed in the Second Appendix hereto; (b) all patents in the Territory issuing from said applications; (c) any additions, divisions, continuations, continuations-in-part, amendments, amalgamations, reissues and re-examinations of such applications or patents in the Territory; (d) any confirmation, importation and registration patents thereof in the Territory, and (e) any extensions and renewals of all such patents and patent applications in the Territory in whatever legal form and by whatever legal title they are granted.

1.12 "Products" means the pharmaceutical preparations for human use in I.V. dosage form, containing the Compound as an active ingredient in the formulation that will be described in the Registration and such other formulations for which MGI exercises its right of first refusal pursuant to Article 2.6. The current formulation as submitted to the Food and Drug Administration of the United States of America in the IND 39,797 Amendment # 64 and to the Therapeutic Products Programme of Canada in the IND 9427-H01336-21C is described in the Third Appendix hereto.

1.13 "Registration" means any official approval, or authorization by the competent Regulatory Authority of each country in the Territory, which is legally required to lawfully market the Products in the Territory, including, without limitation, any governmental price approval or reimbursement approved under a national health insurance system.

1.14 "Regulatory Authority" means, with regard to the United States of America the United States Food and Drug Administration (FDA) and, with regard to Canada the Therapeutic Products Programme, or any other agency which shall be responsible for the issuance of the Registration throughout the term of this Agreement.

1.15 "Territory" means the United States of America and its possessions and territories (Puerto Rico, United States Virgin Islands), and Canada and its provinces, possessions and territories.

1.16 "Trademark' means the trademark DEDYS® or ONICIT®, which are and shall be HHC's property, or under another trademark to be selected by the Parties, it being understood that HHC shall bear reasonable

documented expenses in connection with such selection, and which shall be HHC's property.

ARTICLE 2 - GRANT OF RIGHTS AND COMPETITION

2.1 Subject to all terms and conditions of this Agreement, HHC hereby grants MGI, and MGI hereby accepts, an exclusive, non-transferable and non-assignable (except as provided at Article 2.8 here below with regard to distribution, promotion and sale of the Products in the Field by a local Affiliate of MGI in Canada), royalty-bearing license under the Patents and to use the Know-how, to distribute, promote, market and sell the Products in the Territory for the Field.

Moreover, subject to all terms and conditions of this Agreement, HHC hereby grants MGI, which hereby accepts, an exclusive, non-transferable and non-assignable (except as provided at Article 2.8 here below with regard to distribution, promotion and sale of the Products in the Field by a local Affiliate of MGI in Canada), royalty-bearing license to affix the Trademark to the Products and to use it in connection with the distribution, promotion, marketing and sale of the Products in the Territory for the Field,

2.2 The exclusivity granted pursuant to this Article 2 means that only NMI may be licensed by HHC to distribute, promote, market and sell the Products in the Territory for the Field.

The Parties acknowledge, however, that HHC has or may have other licensing arrangements for the Products outside the Territory, or within the Territory outside the Field, and that as a consequence, Products marketed by third parties may enter the Territory or the Field; provided that HHC shall use commercially

reasonably efforts to include in such other arrangements appropriate provisions prohibiting, to the maximum extent permissible under applicable laws and mutations, that such Products marketed by third parties enter the Territory or the Field, and to enforce such provisions as and when necessary. HHC further undertakes to provide MGI, upon MOTs written request, with a copy of such provisions for the purpose of enabling MGI to verify compliance with this Article 2.2.

2.3 MGI agrees not to knowingly market, ship, distribute, promote, sell or otherwise put into circulation the Products outside the Territory and/or outside the Field and to expressly and consistently inform distributors and/or wholesalers for the Products, by warning letters or other appropriate and effective means, that the distribution and sale of the Products outside the Territory and/or outside the Field is prohibited and to enforce such prohibition as and when necessary. In the event that MGI enters into any agreements with its distributors and/or wholesalers for the Products, it shall use commercially reasonable efforts to include in any and all said agreements appropriate provisions prohibiting, to the maximum extent permissible under applicable laws and regulations, that the Products are distributed outside the Territory and/or outside the Field, and to enforce such provisions as and when necessary. Moreover, MGI undertakes to pass on to HHC any request for the Products coming to MGI from any party or for sale outside the Territory,

2.4 MGI agrees not to, directly or indirectly, research, develop, manufacture, register, sell, promote, or distribute in the Territory any competing product throughout the term of this Agreement, except with

the prior written authorization of HHC, which authorization may be withheld by HHC in its sole and absolute discretion. A "competing product" is hereby defined as any anti-emetic pharmaceutical products or therapies having the same indications of the Products.

2.5 MGI acknowledges and agrees that it shall not have the right to manufacture, directly or indirectly, the Compound and/or the Products. In order to maintain at all times the highest quality for the Products and to ensure a scientifically proper and safe exploitation of the licensed Know-how and Patents and in order to maintain and to protect the goodwill of the Trademark, MGI undertakes to purchase of its Products' requirements exclusively from a source indicated or approved by HHC; provided that such source meets all requirements of applicable Regulatory Authorities and specifications for the Products applicable in the Territory.

2.6 The Parties hereby acknowledge and agree that the development and marketing of an oral formulation of the Compound will be useful for enlarging the market of pharmaceutical preparations containing the Compound in the Field and undertake to discuss in good faith on the timing, costs and any other conditions relevant to the development, registration and marketing of such oral formulation. In addition, HHC shall offer to MGI a first negotiation right for the Territory (or some portion thereof) to distribute, promote, market and sell any new dosage form(s) and/or formulation(s) (other than the I.V. formulation as shall be described in the Registration) of the Products in the Field (i) becoming available to HHC throughout the term of this Agreement and which HHC is free to offer in the Territory (or a portion thereof) or (ii) which development and marketing may be deemed of

interest for the Parties or any of them. MGI shall have a two-month time from notification by HHC to exercise said first negotiation right and to decide, by written election to HHC, whether it is interested in said new dosage form(s) and/or formulation(s) or not. If MGI decides to exercise said first negotiation right, it shall do so by notifying HHC in writing. Upon such notice, the Parties shall discuss and seek an agreement in good faith on the best steps to be taken and on the timing and resources needed to develop, file the relevant application for registration and launch said new dosage form(s) and/or formulation(s) in the Territory, as well as on the royalties, supply prices and any other conditions of supply and marketing of said new dosage form(s) and/or formulation(s), including but not limited to relevant minimum sales obligations. Upon reaching said agreement, this Agreement shall be accordingly amended and fully applicable also with respect to such new dosage form(s) and/or formulations(s), which shall be included in the definition of Products hereunder. If MGI decides not to exercise said first negotiation right or if an agreement cannot be reached within b (six) months from the date of MGI's notification of interest to HHC, HHC shall then be free to fully exploit said new dosage form(s) and/or formulation(s) of the products in the Field with any third party in the Territory, however under a trademark different from and not confusingly similar to the Trademark and provided that HHC shall not offer to such third parties, taking into account all circumstances of the proposed transaction, business conditions which are better than those offered to MGI in connection with said new dosage form(s) and/or formulation(s) and provided further that such exploitation does not conflict with, or otherwise violate the terms and conditions of this Agreement.

2.7 MGI acknowledges that there are or there may be different uses or indications of the Products and that the rights and licenses hereby granted by HHC are limited to the Field. HHC retains the right to, and shall be free to exploit at its own discretion into and outside the Territory, any and all uses or indications of the Products outside the Field, in whichever dosage form and/or formulation HHC may deem fit, including but not limited to I.V., and MGI shall have no rights in any respect whatsoever to such uses and/or indications outside the Field, provided that HHC shall not be entitled to use the Trademark or trademarks which are confusingly similar to the Trademark in respect of marketing and sale in the Territory of said uses and/or indications of the Products outside the Field; provided that such exploitation does not conflict with, or otherwise violate the terms and conditions of this Agreement.

2.8 MGI shall not have the right to sublicense or otherwise transfer any of its rights and/or obligations hereunder; provided that MGI shall be entitled to engage en-promotion partners in the United States, subject to HHC's prior approval, not to he unreasonably withheld. Moreover, MGI shall not have the right to sub-contract any of its rights and/or obligations hereunder, provided however that MGI shall be entitled to have the logistics and warehousing activities (excluding however invoicing and billing to customers) relevant to the Products carried out by its Affiliates or by third parties in the Territory. It is understood that MGI shall have the right to have the Products distributed, promoted and sold in Canada by its local Affiliate, whose name and address, and any change thereof, shall be timely notified to HHC.

MGI undertakes and warrants that its Affiliate in Canada shall strictly comply with MGI's applicable obligations and warranties stated in this Agreement and any breach of such obligations and/or warranties by such Affiliate shall he regarded in all respects and in particular for the purposes of Articles 11 and 17 hereunder, as a breach by MGI. Correspondingly, MGI shall be fully responsible towards HHC for any action and/or omission of its said Affiliate, and shall defend, indemnify and keep HHC wholly free and harmless from any connected claims, damages, liabilities, losses, costs and/or expenses. Moreover, MGI expressly undertakes and warrants that any agreement with respect to the Products between itself and its Affiliate in Canada shall be fully consistent with this Agreement and undertakes to send to HHC, upon HHC's written request, a copy of any said executed agreement (with economic terms redacted) for the purpose of enabling HHC to verify compliance with terms and conditions hereof.

MGI shall be permitted to disclose to its Affiliate in Canada such Know-how and other relevant information to the extent strictly necessary and appropriate to correctly carry out its obligations hereunder, provided however that any such disclosure shall be made only under a confidentiality agreement, for the benefit of and approved in writing by HHC, having terms at least as restrictive as those provided herein.

2.9 MGI shall not enter into any agreement with third parties with respect to the Compound and/or the Products, except as may be necessary for the purpose of a full and collect exploitation of the Products in accordance with all terms and conditions of this Agreement. Upon FMC's written request, MGI shall send to HHC a copy of any said executed agreement

(with economic terms redacted) for the purpose of enabling HHC to verify compliance with terms and conditions hereof. Nothing in this Agreement shall be construed as giving MGI any right to use or otherwise deal with the Know-how, the Patents and/or any other information received hereunder for purposes other than those of distributing, promoting, marketing and selling the Products in the Territory for the Field in accordance with the terms and conditions of this Agreement. In particular, and without limiting the generality of the foregoing, MGI hereby undertakes not to file any application for the Registration of generics of the Products in the Territory or outside the Territory throughout the term of this Agreement.

2.10 MGI shall promptly inform HHC of any misappropriation, or threatened or presumed misappropriation of the Know-how winch comes to its attention. HHC will decide on the steps to be taken after having discussed the case with MGI and MGI shall assist, bearing exclusively its own internal costs and HHC bearing MGI's reasonable out-of-pocket costs, HHC in taking legal action, if deemed necessary by HHC, against such misappropriation.

2.11 Each Party shall promptly and fully inform the other if it has a reasonable basis to believe that there have been unauthorized sales of the Products into or outside the Territory, and shall use practical efforts with all such persons to act consistently with the terms and conditions of this Agreement.

2.12 In the event that MGI fails to respect the limitations of the licenses granted under this Article 2 and MGI or its Canadian Affiliate knowingly distributes Products outside the Territory and/or outside the Field, or fails to enforce appropriate prohibitions on such distribution of Products outside the Territory

and/or outside the Field by its distributors and/or wholesalers in accordance with Article 2.3 here above, MGI shall be deemed to be in material default, and HHC shall have the right, in its sole discretion, to terminate this Agreement by written notice to MGI, which breach is not cured within a sixty (60) days notice period.

ARTICLE 3 - EXCHANGE OF INFORMATION AND IMPROVEMENTS

3.1 Throughout the term of this Agreement, HHC shall supply MGI in writing and free of charge with any relevant Know-how, in addition to that already supplied at the Effective Date hereof, which may be or become available to HHC and which HHC is free to disclose. Notwithstanding the foregoing, nothing in this Agreement shall require HHC to obtain additional Know-how from third parties.

In the event that MGI should require technical assistance in connection with its initial sale of the Products in the Territory, HHC will use its commercially reasonable efforts to assist MGI for reasonable periods of time and at times convenient to HHC.

3.2 MGI shall supply HHC in writing or by any other appropriate support, free of charge, with any and all technical and/or scientific information and data relating to the Products and/or the Compound, as soon as they are or become available to MGI throughout the term of this Agreement. MGI shall communicate any such information and data to HHC and MGI shall use such information and data for the purpose of the distribution, promotion and sale of the Products in the Territory for the Field in accordance with the terms and conditions of this Agreement. HHC shall have the right to use such information and data for the purpose

of its business and to disclose the same to HHC's Affiliates and to HHC's Other Distributors, which in turn shall have the right to use them for the purpose of the distribution, promotion and sale of pharmaceutical preparations containing the Compound outside the Territory and outside the Field in the Territory.

3.3 MGI's rights hereunder shall include any Improvement carried out by or which may he discovered, developed, invented or acquired by HHC, for use in accordance with the terms and conditions of this Agreement.

Any Improvement which may be carried out by or which may he discovered, developed, invented or acquired by MGI, its officers, agents or employees, may be used by MGI for the purpose of the distribution, promotion and sale of the Products in the Territory for the Field in accordance with the terms and conditions of this Agreement and will be promptly disclosed and is hereby automatically licensed free of charge to HHC on an exclusive basis even as to MGI (except for those MGI's activities described here above) and HHC shall have the right to sublicense the above Improvements to HHC's Affiliates and to HHC's Other Distributors for use outside the Territory and outside the Field in the Territory. MGI shall not incur any obligation to any third party which may prohibit or impair its ability to disclose and license Improvements to HHC.

3.4 All Know-how, Improvements and/or other information and data disclosed to MGI hereunder arc at all times and shalt after expiration or termination of this Agreement for any reason remain HHC's sole and exclusive property.

ARTICLE 4 - DEVELOPMENT AND REGISTRATION OF PRODUCTS

4.1 MGI hereby acknowledges and agrees that

4.1.1 at the Effective Date of this Agreement the Products are under development by HHC for the purpose of submitting the relevant Registration application to the Regulatory Authorities of the Territory,

4.1.2 the development of the Products by HHC may be interrupted or discontinued by HHC as set forth in Article 4.2, if said development becomes commercially unreasonable, or the relevant results may be negative or unfavorable,

4.1.3 the development work presently carried out will not necessarily result in the grant of the Registration of the Products and

4.1.4 HHC makes no warranty and nothing in this Agreement may or shall be construed as a warranty by HHC that the Products will obtain the Registration or that a Product can be developed and registered from the Know-how and MGI shall have no claim against HHC arising out of any delay or refusal by the Regulatory Authorities to issue the Registration in any way whatsoever.

4.2 HHC will use commercially reasonable efforts to complete the development of the Products in accordance with the Development Chart attached as Fourth Appendix hereto and, subject to satisfactory development of the Products and provided that no unforeseeable events occur or additional requests are made by the Regulatory Authorities with respect to the development of the Products described in the Development Chart hereto attached, to file the NDA for the Products in the United States of America not later

than 31 December 2002. For the avoidance of doubt, nothing in this Agreement shall require HHC to perform additional testing or additional development work other than as described in the Development Chart attached hereto. In the event the development of the Products is interrupted or discontinued by HHC or the relevant results are negative or unfavorable as mentioned at Article 4.1.2 here above or in the event the Registration of the Products is not granted as mentioned at Article 4.1.3 here above, the Parties shall meet to discuss and seek an agreement in good faith on such additional clinical trials and other development activities as the Parties may deem appropriate and commercially reasonable, including the direct performance and funding by MGI of the further development activities deemed necessary for the registration of the Products, in which case (i) all relevant protocols shall have to be previously discussed with and approved in writing by HHC, (ii) data, information and results arising from said further development shall be the exclusive property of HHC and MGI shall have the right to use them in connection with the distribution, promotion and sale of the Product in the Territory for the Field, (iii) external documented costs and expenses incurred by MGI with third parties in connection with said further development shall be credited by HHC to MGI against payment of royalties on Net Sales as per Article 7.3 here above (provided that in each Accounting Period the sum to be credited to MGI shall not exceed fifty percent of the royalties which would be payable by MGI in respect of said Accounting Period). If such an agreement cannot be reached within six months from beginning of discussions in this regard, then this Agreement shall automatically terminate, and Articles 17.6. 17.7 and 17.8 hereunder shall apply, it being

understood that HHC shall have no obligation, liability or responsibility whatsoever to compensate, indemnify or reimburse MGI for any payments, damages, losses, costs or expenses incurred by MGI in connection with this Agreement or termination hereof and that the payments already effected by MCA at the effective date of termination pursuant to Article 7 hereunder shall be retained by HHC.

4.3 Applications for the Registration in the Territory shall be filed by HHC in its own name and at its own expenses. HHC shall also pay all administrative fees for the maintenance in force of the Registration throughout the term of this Agreement.

4.4 MGI expressly acknowledges and agrees that HHC is and shall at all times remain the sole and exclusive owner of the Registrations and that ownership of said Registrations and any and all rights, title and interest (including any accompanying goodwill) are, and shall at all times remain, vested in HHC.

4.5 After approval of the NDA for the Products in the United States and compliance by MGI with the provision of Article 7.1.5 hereunder, MGI shall be appointed by HHC as HHC agent with respect to the NDA for the Products in the Field ("FDA Agent) and shall manage and carry out on behalf of HHC all relevant communications and relations with the FDA. in addition, MGI shall be entitled to participate in all negotiations and discussions between HHC and the FDA regarding any labeling for the Products in the Field and shall perform and carry out all post-Registration activities, requested by the FDA, connected with the NDA For the Products in the Field with the exception of those activities specifically listed in the Fifth Appendix hereto, which shall be performed and carried out by HHC. Nothing in this Agreement

precludes HHC from appointing an FDA Agent on different NDAs for products other than the Products (including, without limitation, any new dosage form(s) and/or formulation(s) of the Products in the Field under the terms provided at Article 2.6 hereabove) or for the Products outside the Field or from changing HHC's corporate agent in the United States ("U.S. Agent") at any time.

All said activities, communications and relations as well as MGI's role of HHC's FDA Agent as described above shall be performed by MGI in close coordination with HHC, directly or through third parties, as the holder of the Registrations. In particular, MGI shall copy within 48 hours and keep HHC fully and promptly informed, throughout the term of this Agreement, of all communications received from the Regulatory Authorities of the Territory concerning the Products and/or the Compound. Without prejudice to full compliance by both Parties with any obligations established by applicable laws and regulations of the Territory with regard to adverse events reporting and any other deadlines set by Regulatory Authorities, any and all communications to Regulatory Authorities relevant to the Compound and/or the Products and connected with the activities described above, shall be sent by MGI only after the relevant contents have been discussed with and approved in writing by HHC, which approval shall be deemed to have been given if HHC does not otherwise respond within ten working days in Switzerland of receipt of such proposed communication; provided however, that MGI shall not he required to obtain such prior approval with respect to those mutually agreed routine administrative communications with the FDA. MGI further undertakes and warrants that it shall at all times strictly comply with any and all laws, rules and regulatory requirements in

force in the Territory in connection with the activities, communications and relations contemplated herein.

4.6 MGI shall store and distribute, and shall cause the Products to be stored and distributed according to applicable current Good Manufacturing Practice or any other applicable laws and regulations. MGI shall permit HHC's representatives, during normal business hours and upon three business days advance notice in writing, to inspect those areas of the warehouses of MGI, its Affiliates and distributors where the Products are stored, for the purpose of verifying compliance with applicable laws and regulations as well as with this Agreement

4.7 If material alterations, modifications or amendments of this Agreement or of the Products are imposed by any Regulatory Authority as prerequisites for the grant or the continuation of the Registration of any of the Products, or if Registration of any of the Products is suspended or withdrawn by any said Regulatory Authority, each Party shall notify the other promptly after receipt of notification from such Regulatory Authority and the Parties shall endeavor to agree upon a reasonable and mutually acceptable resolution thereof In the event that the Parties are unable to agree upon such a resolution, HHC shall have the right at its sole discretion, upon written notice to MGI, to delete the Product or Products in question from this Agreement or to take any other measure which it reasonably deems necessary or advisable and, if necessary, to terminate this Agreement, in which case the consequences provided for at Article 17.6, 17.7 and 17.8 hereunder shall apply, it being understood that in any case, except as expressly provided in Article 11 of this Agreement, HHC shall

have no obligation, liability or responsibility whatsoever to compensate, indemnify or reimburse MGI for any payments, damages, losses, costs or expenses incurred by MGI in connection with this Agreement or termination hereof and that the payments already effected by MGI at the effective date of termination pursuant to Article 7 hereunder shall be retained by HHC.

4.8 MGI shall collaborate with and assist HHC and/or any of HHC's Other Distributors for the purpose of obtaining Registrations outside the Territory and/or, outside the Field in the Territory. Such collaboration and assistance shall include, but not be limited to, doing all such acts as may be required by HHC for the purpose of permitting access and maximum use by HHC and/or HHC's Other Distributors of the documentation and results of the activities described at Article 4.5 hereabove and of development work on the Products carried out by MGI pursuant to Article 5.3 here below. HHC shall reimburse MGI for reasonable out-of-pocket expenses incurred in providing such collaboration and access.

4.9 Each Party undertakes to give the other Party Full, accurate and prompt information in writing with regard to adverse events associated with the use of the Products, whether or not ascertained to be definitely attributable to the Products or the Compound, in strict accordance with the procedures and rules established in the Sixth Appendix attached to this Agreement.

4.10 In the event of a recall, complaint, field alert, product withdrawal relevant to the Products marketed by MGI in the Territory, the Parties shall strictly follow the procedures and rules established in the Seventh Appendix to this Agreement.

4.11 MGI shall permit HHC and/or any authorized representative or consultant of HHC to enter MGI's premises, as well as the premises of MGI's Affiliates and/or distributors in the Territory, during normal business hours and upon at least three (3) business days advance notice, to audit and verify compliance by MGI, its Affiliates and distributors with regulatory and other requirements in force in the Territory, as well as with this Agreement, with respect to all aspects related to Registration and to correct and safe distribution, promotion, marketing and sale of the Products in the Territory or in connection with any recall contemplated by Article 4.10 hereabove.

Such audit shall include, without limitation, the right to examine any internal procedures or records of MGI, its Affiliates and distributors relating to the Products. MGI shall give and shall cause its Affiliates and distributors to give, all necessary assistance for a full and correct carrying out of the audit by HHC. No such monitor and/or audit by HHC shall relieve MGI, its Affiliates and distributors of any of their obligations under this Agreement in any way whatsoever.

In the event that any Regulatory Authority or any other competent authority of the Territory carries out or gives notice of its intention to carry out any inspection or audit of MGI, its Affiliates or distributors or otherwise takes any action in relation to the Products, MGI shall immediately notify HHC in full details and shall use commercially reasonable efforts to insure that HHC shall have the right to be present at and to participate in any such inspection or audit.

ARTICLE 5 - POST-REGISTRATION DEVELOPMENT

5.1 HHC shall use commercially reasonable efforts to provide any further clinical and product development that may be requested by any Regulatory Authority in the Territory for the maintenance of the Registration.

to market Products more effectively in the territory.

5.3 MGI shall not undertake nor carry out any trial relevant to the Products without the prior written approval of HHC. MGI shall perform and fund any trials mentioned at article 52 hereabove in accordance with a development plan to be agreed upon in advance with HHC. All relevant protocols shall have to be discussed and approved in writing by HHC. Any and all data, information and know-how, whether patentable or not, arising from said trial will be promptly disclosed and is hereby automatically licensed free of charge to HHC on an exclusive basis even as to MGI (provided that MGI shall have the right to use such data, information and know-how solely for the purpose of the distribution, promotion and sale of the Products in the Territory for the Field in accordance with the terms and conditions of this Agreement) and HHC shall have the right to sublicense said data, information and know-how to HHC's Affiliates and to HHC's Other Distributors for use outside the Territory and outside the Field in the Territory. MGI shall not incur any obligation to any third party which may prohibit or impair its ability to disclose and license said data, information and know-how to HHC. In addition, HHC shall use commercially reasonable efforts to put at MGI's disposal for use in the distribution, promotion, marketing and sale of the Products in the Territory for the Field in accordance

with the terms and conditions of this Agreement, any post-registration trial carried out by HHC's Other Distributors with regard to the Products.

ARTICLE 6 - TRADEMARK OF PRODUCTS

6.1 The Products shall he distributed, promoted, marketed and sold by MGI in the Territory exclusively under the Trademark.

6.2 MGI shall use the Trademark exclusively in connection with and for the purpose of the distribution, promotion, marketing and sale of the Products for the Field in the Territory. MGI acknowledges that it shall be entitled to no rights whatsoever in the Trademark except as is specifically granted pursuant to this Agreement and then only to the extent of the express grant.

6.3 HHC shall register MGI, and MGI shall assist HHC in having MGI registered, as a licensee in the Trademark Register of the Territory as necessary and useful, in particular regarding the recordation as "Registered User" where corresponding legal provisions exist. Such registration shall be cancelled after expiration or termination of this Agreement for any reason upon the request of HHC.

6.4 HHC's trade name and logo shall appear on all Products packaging, labels and inserts and other materials which MGI uses for the distribution, promotion, marketing and sale of the Products in such form and manner as shall he approved by HHC in writing in compliance with all requirements of applicable Regulatory Authorities.

6.5 MGI shall make no use of the Trademark except in the form and with the graphics authorized in advance by HHC. MGI shall for each use feature a

prominent notice and acknowledgement of the registered Trademark ownership and license by WIC in conjunction with all usage of the Trademark. HHC shall have the right to review and approve all intended uses of the Trademark in any packaging, inserts, labels, promotional or other materials relating to the Products prior to actual use thereof.

6.6 MGI will not alter, obscure, remove, conceal or otherwise interfere with any markings, names, labels or other indications of the source of origin of the Products which may be placed by HHC on the Products.

6.7 MGI will not use nor apply for registration of any trademark, trade-name or logo in connection with the Products, nor shall it use or apply for registration of any trademark, logo or design which includes the Trademark, atone or in combination, in or outside the Territory, without the prior written authorization of HHC, which authorization HHC may withhold in its sole and absolute discretion.

6.8 Nothing contained in this Agreement shall be construed as giving MGI a right to use the Trademark or portions thereof or any word confusingly similar to the Trademark or the name "Helsinn" as MGI's corporate name or any part thereof. Throughout the term of this Agreement and thereafter, MGI shall not use nor apply for registration of, any mark, logo or design, in or outside the Territory, which is, or is likely to be, confusingly similar to, or could cause deception or mistake with respect to, the Trademark or to the name "Helsinn" on any pharmaceutical or chemical or healthcare product or service.

6.9 Nothing contained in this Agreement shall be construed as giving MGI the right to use the Trademark outside the Territory or for any other product than the Products and HHC may use, or license others to use, the Trademark in all jurisdictions outside the Territory.

6.10 The Trademark shall always be used together with the sign "R" or the sign "TM" or such other customary symbol or legend which identifies correctly the status of the Trademark.

6.11 MGI recognizes the exclusive rights of HHC regarding the Trademark and acknowledges that it shall not acquire any rights in respect of the Trademark of HHC in relation to the

6.12 HHC shall keep in force the Trademark by paying the necessary fees throughout the term of this Agreement and by using all reasonable efforts to defend any action or proceeding for cancellation of the Trademark, bearing the whole cost thereof and MGI shall render any reasonable assistance in this respect.

6.13 MGI shall promptly notify HHC of any threatened or presumed significant counterfeits, copies, imitations, simulations of, or infringement upon, the Trademark or the name "Helsinn" or of any other act of unfair competition which comes to its attention. HHC will decide on the steps to be taken after having discussed the case with MGI and MGI shall give its full co-operation therefor at HHC's expense. Should it occur that HHC for any reason decides not to defend the Trademark, then MGI shall have the right to take appropriate action for defending the Trademark in its own name with the consent of HHC. In such case, MGI shall bear all the costs and shall be entitled to retain any compensation paid by third persons in this respect

6.14 MGI acknowledges that HHC has no adequate remedy under this Agreement or at law in the event that MGI were to use the Trademark in a manner not authorized by this Agreement and that HHC would, in such circumstances, be entitled to specific performance, injunctive or other equitable relief, including interlocutory and preliminary injunctive relief.

6.15 MGI shall be entitled to mark the Products packaging, labels and inserts with the MGI name and logo, in a manner reasonably acceptable to HHC.

ARTICLE 7 - COMPENSATIONS BY MGI

7.1 As consideration for the right granted and information disclosed under this Agreement, in addition to the amount of USD5,000,000 (United States Dollars five million) which has been paid by MGI to HHC in accordance with the Letter of Intent mentioned at recital (d) here above, MGI shall pay to HHC, upon occurrence of the following events, the following milestone payments, which shall not be refundable nor creditable towards future royalties:

7.1.1 At signature of this Agreement MGI shall pay to HHC USD6,000,000 (United States Dollars six million), of which up to 50% may, at MGI's option, be paid in freely tradable shares of MGI common stock as better specified at Article 7.2 hereunder;

7.1.2 Six months after execution of this Agreement, MGI shall pay to HHC USD2,000,000 (United States Dollars two million);

7.1.3 At Type B pre-NDA meeting with the FDA, MGI shall pay to HHC USD4,000,000 (United States Dollars four million);

7.1.4 At NDA filing in the United States of America, MGI shall pay to HHC USD10,000,000

(United States Dollars ten million) of which up to 50% may, at MGI's option, be paid in freely tradable shares of MGI common stock as better specified at Article 7.2 hereunder,

7.1.5 At NDA approval in the United States of America, MGI shall pay to HHC USD 11,000,000 (eleven million).

The above milestone payments shall be paid by MGI to HHC by wire transfer of immediately available funds to an account designated in writing by HHC; provided that the payments described at Articles 7.1.2 and 7.1.3 shall be paid pursuant to the terms of an Escrow Agreement among the Parties and U.S. Bank Trust Association in the form attached as Appendix 8 hereto, dated as of the Effective Date hereof. The milestone payments described at Articles 7.1.1, 7.1.2, 7.1.3, 7.1.4 and 7.1.5 shall be paid within 15 (fifteen) days of occurrence of the relevant event. Failure to pay any of the milestones on a timely basis shall entitle HHC to terminate this Agreement if MGI fails to cure such breach within a 15 (fifteen) days notice period.

7.2 MGI agrees to promptly inform HHC in writing as soon as it elects to effect part of the milestone payments under Articles 7.1.1 and 7.1.4 hereabove in freely tradable shares of MGI common stock. In this case, MGI shall issue to HHC such number of freely tradable shares of MGI common stock calculated by dividing the amount to be paid in MGI common stock by the average of the closing prices for such MGI common stock (as reported in The Wall Street Journal or, if not reported therein, in another mutually agreed upon authoritative source) for the 30 (thirty) trading days before the date of payment of the related milestone payment (the "Original Price"). MGI shall deliver the certificate representing such shares to

HHC by overnight courier within five (5) business days after such date of payment. Such shares shall be duly authorized, validly issued, fully paid and non-assessable and shall he free and clear of any and all liens, claims or other encumbrances. Notwithstanding anything contained herein to the contrary, MGI shall not be entitled to elect to satisfy its payment obligation under Articles 7.1.1 or 7.1.4, as the case may be, in freely tradable shares of MGI common stock, if, at the time that the payment becomes due pursuant to Article 7.1.1 or Article 7.1.4 above, as the case may be, the Continued Listing - Standard 2. HHC acknowledges that any shares received from MGI in payment of its milestone payment obligations under Articles 7.1 or 7.1.4 of this Agreement will be "restricted securities" within the meaning of Rule 144 under the U.S. Securities Act of 1933, and that such shares will not be transferable in the U.S. markets unless and until such shares are either registered under the U.S. Securities Act of 1933 or an exemption from such registration requirement is available. MGI agrees that, unless a registration statement enabling such shares to be freely tradable by HHC upon receipt has been filed by MGI and declared effective by the U.S. Securities and Exchange Commission and HHC has received reasonable assurances that MGI will maintain the effectiveness of such registration statement until HHC fully liquidates such shares in accordance with the restrictions contained in the last sentence of this Article 7.2, in each case prior to the date of delivery of such shares, then MGI shall not be entitled to elect to make part of the milestone payment under Articles 7.1.1 or 7.1.4 in shares of MGI common stock. MGI and HHC hereby acknowledge that, in connection with any such registration of shares of MGI common stock, MGI and HHC will use their

reasonable best efforts to negotiate in good faith a registration rights agreement for such registration on terms reasonable and customary for such agreements. MGI agrees that, if and to the extent that HHC sells any shares of MGI common stock received hereunder on the NASDAQ/NMS (or on any securities exchange or other public trading market on which MGI's common stock is then traded) at a price (the "Sale Price") that is less than the Original Price applicable to those shares, then MGI shall make a cash payment to HHC in United States Dollars equal to the difference between the applicable Original Price and the Sale Price, multiplied by the number of shares sold by HHC at that Sale Price; provided, however, that MGI's obligation to make such payments shall terminate and not apply to any sale of shares by HHC occurring after the day on which, assuming HHC were selling as many shares as possible each day subject to the volume limitations described hereunder in this Article 7.2, HHC could have disposed of all of its shares in such market. MGI shall pay such amount via wire transfer of same day funds within five days after receipt from HHC of evidence of such sale reasonably satisfactory to MGI Notwithstanding the filing and effectiveness of such registration statement, HHC agrees that, in connection with any sale of such MGI shares on the NASDAQ/NMS (or on any securities exchange or other public trading market on which MGI common stock is then traded), the number of shares of MGI common stock sold by HHC on any day will not exceed 10% (ten percent) of the average daily trading volume of MGI common stock in that market for the five trading day period ending two trading days prior to the date of such sale; provided, however, that (i) any shares sold by "HHC in one or more block sales of at least 20,000 shares each which are effected

through a market maker for MGI common stock shall not be counted for purposes of the foregoing volume limitations, and (ii) such volume limitations shall however not apply to the extent that they require HHC a period longer than 90 (ninety) days from the first sale of MGI's shares by HHC to sell MGI's shares.

7.3 In addition to the above milestone payments, MGI shall pay running royalties as follows:

7.3.1 in consideration of the license granted hereunder on the Know-how, MGI shall pay to HHC or HHC's nominee a royalty of 3% (three percent) on all Net Sales throughout the term of this Agreement. It is expressly agreed that in case the Know-how becomes publicly known other than by action of HHC, the above royalty shall continue to be payable throughout the term of this Agreement, without prejudice to the payment to HHC of additional damages in case the Know-how becomes publicly known by the action of MGI.

7.3.2 In consideration of the license granted hereunder on the Patents, MGI shall pay to HHC or HHC's nominee a royalty of 2% (two percent) on all Net Sales until expiration of all said Patents, on a county-by-country basis.

7.3.3 In consideration of the license granted hereunder on the Trademark, MGI shall pay to HHC a royalty of 3% (three percent) on all Net Sales throughout the term of this Agreement.

7.3.4 Royalties due by MGI pursuant to this Article shall accrue in United States Dollars (with regard to sales in the United States of America) and in Canadian Dollars (with regard to sales in Canada) and payments shall be made by wire transfer of immediately available funds to an account designated in

writing by HHC in United Slates Dollars (or in Canadian Dollars, as applicable) within 30 (thirty) days after the end of each Accounting Period, in respect of the Net Sales achieved in that Accounting Period. Without prejudice to HHC's right to be paid in accordance with the provisions hereof as well as to any other remedy which may be available to HHC in accordance with this Agreement and/or applicable law, late payments shall bear interests at the prime rate applicable in Switzerland as of the date such payment was originally due.

7.3.5 For the purpose of computing the volume of the Net Sales, the Products shall be deemed to have been sold by MGI or its Affiliates as mentioned at Article 2.8 hereabove on the date of invoicing or on the date of delivering, whichever is first to

7.3.6 Notwithstanding anything contained in this Agreement, during the term of this Agreement MGI shall effect an annual minimum payment equal to 7% (seven percent) of the minimum annual sales established in the Ninth Appendix hereto but only to the extent that the amount so payable annually is greater than the overall amount that would otherwise be payable by MGI pursuant to Articles 7.3.1, 7.3.2 and 7.3.3 above. In the event that MGI does not effect said minimum annual payment within 31st January of the following year throughout the term of this Agreement, HHC shall have the right to terminate this Agreement as set forth in Article 17.4 below.

7.3.7 MGI will add Value Added Tax (VAT) if any, as and where provided by law, to all the royalty accounts rendered and pay such VAT directly to the competent authorities under its own responsibility, or, where so provided by law, mark the royalty accounts

with the notice: "VAT zero rated", stating the title of the exemption or exclusion.

7.3.8 If any official authorization shall be required to enable MGI to effect any payments of compensations due and payable hereunder, MGI shall use its best efforts to secure such authorization within the times stipulated in this Article, and in the event that by reason of such authorization not having been granted the payment is delayed beyond the times so stipulated, MGI shall so advise HHC and shall effect payment by any other lawful means indicated by HHC; failing such indications, MGI shall effect payment within 15 (fifteen) days of such authorization being granted.

7.4 All payments lo be made pursuant to this Agreement represent actual amounts that HHC is entitled to receive and shall not be subject to any deduction for any reason whatsoever. In the event that such payments become subject to duties, taxes or charges of whatever kind or nature (excluding taxes am HHC"s income), such payments shall be increased to such an extent as to allow HHC to receive the net amounts due under this Agreement.

7.5 MGI shall in no case be entitled to off set or otherwise withhold any payment due to HHC hereunder in view of possible, justified or unjustified, claims against HHC.

7.6 If there exists a tax treaty to avoid double taxation between Switzerland and the Territory which reduces the standard rate of withholding tax, MGI shall assist HHC in obtaining the necessary exemption of the withholding tax according to such treaty. Upon submission by HHC of adequate exemption forms or equivalent, if required, MGI shall deduct only

such reduced withholding tax from its payments to HHC and shall submit to HHC the corresponding receipts so that HHC may collect these amounts from its own tax authorities as a tax credit.

ARTICLE 8 - MARKETING AND SALE OF PRODUCTS

8.1 MGI hereby undertakes that it will launch the Products in the Field onto the whole market of each country of the Territory as soon as possible and in any case no later than 6 (six) months from respective Registration and availability of the necessary commercial supply, and that it shall promptly communicate in writing the relevant launching dates to HHC.

8.2 MGI shall be entitled to resell the Products to its customers in the Territory at such prices as it may determine subject to all applicable laws of the Territory. MGI shall keep HHC fully and timely informed on the price of the Products in the Territory and shall promptly notify any change thereof.

8.3 MGI hereby undertakes and warrants that it shall distribute, promote, market and sell the Products throughout the Territory under its corporate name and responsibility and at its own expense. MGI also undertakes and warrants that distribution, promotion, marketing and sale of the Products in the Territory shall fully comply with all laws, regulations and requirements at any time being in force in the Territory and shall be fully consistent with the conditions and requirements of the Registration.

8.4 Marketing, advertising and promotional materials concerning the Products and training manuals for MGI's medical representatives shall be developed and prepared by MGI at its own expense and in coordination with HHC, which shall render reasonable

assistance in this respect. HHC shall have the right to review and approve the final draft of any said material in advance of print thereof, for the purpose of ensuring compliance of said materials with the international profile and marketing strategy of the Product and the Compound, provided that approval by HHC shall be deemed to have been given if HHC does not otherwise respond within ten working days in Switzerland of receipt of such materials.

8.5 MGI shall promote and distribute the Products in accordance with the Product profile and positioning reviewed with HHC and shall regularly supply HHC not later than September 30 in each year throughout the term of this Agreement with its marketing and promotion plans which shall be discussed in good faith with HHC and shall have to be approved in writing by HHC, which approval shall not be unreasonably withheld or delayed. A marketing strategy for the Products shall he developed and prepared by MGI consistent with the Registration and with the international profile of the Products as established by HHC. MGI shall keep HHC informed on all its promotional and marketing activities in the Territory regarding the Products and periodic meetings shall be organized between the Parties in order to discuss any and all aspects relevant to the promotion and marketing of the Products in the Territory.

8.6 MGI shall promptly supply HHC free of charge with original copies, in accordance with HHC's reasonable requests, of all marketing, advertising and promotional materials relevant to the Products and of the training manuals for its medical representatives and subject to Article 14.5, HHC shall be free to use, directly or indirectly, any such material for its business inside the Field outside the Territory. In no

event shall HHC have the right to use such material in the Territory whether inside or outside the Field.

8.7 MGI undertakes to fully develop and pursue the market for the Product in the Field throughout the Territory. Throughout the term of this Agreement, MGI shall, at its own expense, maintain an active sales organization for marketing and selling the Products in the Field throughout the Territory, maintain an adequate and representative stock of the Products to meet market demand in the Territory and undertakes to effectively distribute, advertise, market, sell and promote the sale and use of the Products in the Field throughout the Territory. In particular, and without limiting the generality of the foregoing obligations, MGI shall perform at least the promotion and marketing activities described in the Tenth Appendix hereto and shall secure annual minimum sales of the Products corresponding, in each of the 5 (five) years starting from the second year from launch, as least to 85% (eighty-five percent) of MGI's unit sales base forecast for said year with regard to the United States of America, which is enclosed in the Ninth Appendix to this Agreement. Prior to the expiration of the fourth year of such sates base forecast, the Parties shall discuss in good faith and seek an agreement an annual minimum sales in the United States of America for the remaining term of this Agreement. If such an agreement cannot be reached within the above deadline, then annual minimum sales for the remaining term of this Agreement shall correspond at least to 85% (eighty-five percent) of MGI's unit salts base forecast for said years with regard to the United States of America, which is enclosed in the Ninth Appendix to this Agreement Minimum sales levels with regard to Canada shall be discussed in good faith

by the Parties after a final decision has been made by HHC on the Registration of the Product in Canada.

8.8 MGI shall, within September 30th in each year throughout the term of this Agreement, provide HHC with an annual sales forecast in units for each of the Products. It is also agreed that MGI shall develop and supply HHC with sales forecast for 3 (three) years, starting from the date of Registration and revised annually.

8.9 MGI shall make clear in all dealings with its customers and prospective customers that it is acting as licensee and distributor of the Products and not as agent of HHC.

8.10 The final package of the Products, as well as any change thereof, shall be discussed in good faith and mutually agreed by the Parties and shall comply with all requirements of applicable Regulatory Authorities.

8.11 All packaging, insert sheets, labels, advertising and other materials relevant to the Products shall bear the notice "Distributed under license from Heisinn Healthcare SA, Switzerland", in such form and manner as HHC may deem appropriate subject to any applicable regulatory requirements in the Territory.

ARTICLE 9 - RECORDS AND REPORTS

9.1 MGI shall submit to HHC together with each royalty payment a written royalty statement signed by a responsible officer of MGI which shall show the units of Products sold or otherwise disposed of by MGI, the unit price, the gross sales and the Net Sales of each of the Products, its stock of Products, the quantity of distributed free medical samples, a detailed listing and appropriate evidence and rationale of any and all

discounts granted for each client, wholesaler and/or distributor and any other relevant information in sufficient detail to permit to HHC to determine and verify the royalties due to HHC. Throughout the term of this Agreement and for a period of at least 3 (three) years thereafter, MGI shall keep complete and accurate books, records and accounts in accordance with sound accounting practice covering all its operations hereunder as necessary to determine and verify the units of Products sold or otherwise disposed of by MGI, the gross sales and the Net Sales and the amount of royalties due to HHC. HHC shall have the right, at any time throughout the term of this Agreement and for a period of three years thereafter, during normal business hours and upon at least three (3) business days advance notice, to have such books, records and accounts inspected and audited by its duly authorized representatives or, at HHCs discretion, by an independent certified public accountant to be nominated by HHC and reasonably acceptable to MGI. MGI shall fully co-operate with HHC, its authorized representatives or independent certified public accountant and make available all work papers and other information reasonably requested in connection herewith. In the event the inspection or audit reveals that MGI's reports are not in accordance with actual sales and that an underpayment has occurred, MGI shall immediately pay to HHC any underpaid royalties within 10 (ten) days of the date HHC delivers to MGI the relevant inspection or audit report In case of an underpayment of at least five percent (5%) of the amounts owing during the audited period, MGI shall also bear all the costs of the inspection or audit and any overdue amounts hereunder shall bear interest at the prime rate applicable in Switzerland as of the date such payment was originally due.

9.2 Within 10 (ten) working days in the United States of America from the end of each month throughout the term of this Agreement, MGI shall supply HHC with a written report showing the units of Products sold and the units of free medical samples distributed during such month in the Territory.

9.3 MGI shall promptly provide HHC with written reports of any importation or sale of any pharmaceutical preparation containing the Compound in the Territory of which MGI has knowledge from any source other than HEM, as well as with any other information which HHC may reasonably request in order to be updated on the market conditions in the Territory.

ARTICLE 10 - REPRESENTATIONS AND WARRANTIES

10.1 HHC hereby represents and warrants to MGI as follows:

10.1.1 HHC has been duly organized and is validly existing as a corporation in good standing under the laws of Switzerland. HHC has the corporate power and authority to enter into this Agreement and to consummate the transactions contemplated by this Agreement.

10.1.2 The execution, delivery and performance of this Agreement, and the consummation of the transactions contemplated by this Agreement, by HHC have been duly and validly authorized by all requisite corporate actions. This Agreement constitutes a legal, valid and binding agreement of HHC enforceable against HHC in accordance with its terms.

10.1.3 The execution, delivery and performance by HHC of this Agreement requires no action by or in

respect of, or consent or approval of, or filing with any Governmental Authority.

10.1.4 The execution, delivery and performance by FDIC of the contemplated transactions do not and will not (A) contravene or conflict with the charter or bylaws of HHC, as applicable, (B) contravene or conflict with or constitute a violation of any provisions of any applicable law binding upon HHC, or (C) constitute a default in any material respect under or give rise to any right of termination, cancellation or acceleration of, or to a loss of any material benefit to which HHC is entitled.

10.1.5 There is no action, suit, investigation or proceeding pending against, or to the knowledge of HHC, threatened against or affecting, HHC before any court, arbitrator or any governmental authority, including but not limited to Regulatory Authorities, that in any manner challenges or seeks to prevent, enjoin, alter or materially delay the contemplated transactions, and, to the knowledge of HHC, there is no reasonably valid basis for any such action, suit investigation or proceeding to be brought.

10.1.6 The persons executing this Agreement on behalf of HHC are duly authorized to do so and by so doing have bound HHC to the terms and conditions of this Agreement.

10.1.7 WIC has received no notice from any of third party licensors that it is in material breach of any of its obligations under the Syntex Agreement, and it is not aware of any material breach of the Syntex Agreement. The Syntex Agreement constitutes a legal, valid and binding agreement of HHC, enforceable against HHC in accordance with its terms.

10.1.8 HHC has licensed sufficient rights to the Patents and Know-how under the Syntex Agreement and, other than the grant of license to third party manufacturers, HHC has not assigned and/or granted licenses to the Patents or Know-how in the Territory for the Field, or entered into any inconsistent prior obligations, to any other person or entity that would restrict or impair the rights granted hereunder to MGI.

10.1.9 To the actual knowledge of HHC, (i) as of the Effective Date hereof the Patents are valid and in full force and (ii) as of the Effective Date hereof it is not aware of any existing or pending patents of third parties which would be infringed by the marketing and sale of the Products in the Field in the Territory in accordance with all terms and conditions of this Agreement.

10.1.10 None of the materials provided to MGI pursuant to its due diligence requests contained any untrue statement of material fact.

10.2 MGI hereby represents and warrants to HHC that:

10.2.1 MGI is a corporation duly incorporated, validly existing and in good standing under the laws of the state of its incorporation and has all corporate powers and all governmental licenses, authorizations, consents and approvals required to carry on its business as now conducted and as contemplated to be conducted in connection with the transactions contemplated by this Agreement (the "Contemplated Transactions"). MGI is duly qualified to do business as a foreign corporation in each jurisdiction where the character of the property owned or leased by it or the nature of its activities (after giving effect to the

Contemplated Transactions) make such qualification necessary to carry on its business except where the failure to so qualify would not have a material adverse effect on MGI.

10.2.2 The execution, delivery and performance by MGI of this Agreement and the consummation by MGI of the Contemplated Transactions are within the corporate powers of MGI, and have been duly authorized by all necessary corporate action on the part of MGI. Each of this Agreement and the Escrow Agreement constitutes a legal, valid and binding agreement of MGI, enforceable against MGI in accordance with its terms.

10.2.3 The execution, delivery and performance by MGI of this Agreement requires no action by or in respect of, or consent or approval of or filing with, any Governmental Authority, other than filings with the SEC in fulfillment of MGI's disclosure obligations under U.S. securities laws.

10.2.4 The execution, delivery and performance by MGI of the Contemplated Transactions do not and will not (A) contravene or conflict with the charter or bylaws of MGI, as applicable, (B) contravene or conflict with or constitute a violation of any provisions of any Applicable Law binding upon MGI, or (C) constitute a default in any material respect under or give rise to any right of termination, cancellation or acceleration of, any agreement or instrument to which MGI is a party, or to a loss of any material benefit to which MGI is entitled.

10.2.5 There is no action, suit, investigation or proceeding pending against, or lo the knowledge of MGI, threatened against or affecting, MGI before any court, arbitrator or any governmental authority,

including but not limited to Regulatory Authorities, that in any manner challenges or seeks to prevent, enjoin, alter or materially delay the Contemplated Transactions, and, to the knowledge of MGI, there is no reasonably valid basis for any such action, suit investigation or proceeding to be brought.

10.2.6 As of February 28, 2001, the authorized capital stock of MGI consists of 30,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of February 28, 2001, (i) 16,538,545 shares of MGI's common stock are issued and outstanding, (ii) no shares of MGI's common stock are issued and held in the treasury of MGI and (iii) 4,075,749 shares of MGI's common stock are reserved for issuance upon exercise of options, warrants, convertible securities or any other right to acquire shares of common stock. There are no shares of preferred stock outstanding or reserved for issuance upon exercise or conversion of options. The common stock to be issued to HHC in accordance with the terms of this Agreement, if, any, will be, when so issued, duly authorized, validly issued and outstanding and fully paid and non-assessable. Such shares of common stock shall be freely tradable by HHC and shall not be subject to any preemptive rights.

10.2.7 MGI has heretofore delivered to HHC MGI's Form 10-K for the year ended December 31, 2000 ("10-K") and each and every report filed with the United States Securities and Exchange Commission ("SEC") since the date thereof. As of its date, except for any information corrected or superseded by subsequent filings with the SEC, such reports did not contain any untrue statement of material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of

the circumstances under which they were made, not misleading. The audited consolidated financial statements of MGI and its subsidiaries, and the notes thereto included in the 10-K have been prepared in accordance with GAAP and present fairly the consolidated financial position of MGI and its subsidiaries as of the date thereof and the results of their consolidated operations and changes in consolidated financial position for the periods then ended. The unaudited consolidated financial statements included in MGI's 2000 quarterly reports filed on Form 10-Q ("10-Q") comply as to form in all material respects with the published rules and regulations of the SEC with respect thereto; and such unaudited financial statements are fairly presented in conformity with generally accepted accounting principles (except as permitted by Form 10-Q) applied on a basis substantially consistent with that of the audited financial statements included in the 10-K, subject to normal year-end adjustments. Except as and to the extent reflected or reserved against in the balance sheet included in the 10-K or 10-Qs, in the notes thereto or as covered by valid and collectible insurance or other collectible claim for reimbursement, except as set forth in a Schedule referred to in this Agreement or in a press release issued by MGI since the tiling of the most recent 10-Q, there has been no material adverse change in the business, properties or financial condition of MGI and its subsidiaries taken as a whole,

10.2.8 The persons executing this Agreement on behalf of MGI are duly authorized to do so and by so doing have bound MGI to the terms and conditions of this Agreement.

10.2.9 MGI understands and acknowledges that, as of the Effective Date hereof, there is no assurance

that there is or will be a market for the Products, and MGI expressly assumes the risk that the Products will be commercially marketable. HHC shall have no liability to MGI of any kind, nor shall MGI be entitled to a return or a refund of any portion of the payments specified at Article 7 hereof if, for any reason, the Registration is not granted in any part or the whole of the Territory or a commercial market does not develop for the Product.

10.2.10 MGI has been given full and complete access to such information and records of HHC as it deemed appropriate to conduct due diligence and such due diligence has been performed to the full satisfaction of MGI.

ARTICLE 11 - LIABILITIES, INDEMNITIES AND INSURANCE

11.1 MGI shall he fully liable for and shall defend, indemnify and hold HHC and its Affiliates, officers, directors and employees wholly free and harmless from and against any and all liabilities, damages, losses, costs, taxes, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgements or administrative and judicial orders arising out of or resulting from any claim, suit or proceeding to the extent arising out of or resulting from (a) the use of the Know-how, the Trademark and the Patent in the Territory by MGI (except to the extent provided in Article 11.2 below); (b) any failure by MGI, its local distributors or Affiliates to comply with any applicable laws, regulations and/or administrative decision regarding the Registration and/or the Products; (c) the performance by MGI of its obligations as HHC's FDA Agent and/or the management and performance by MGI of the post-Registration activities connected with

the NDA for the Products, as described at Article 4.5 above; (d) the performance by MGI or its agents of the development work relevant to the Products as described at Article 5.3 above; (e) any defect in the results of the development work carried out by or on behalf of MGI as provided at Article 5.3 above; (f) the storage, distribution, sampling, record-keeping, analysis, transfer or sale of the Products by MGI or its agents; (g) the promotion, advertising and marketing of the Products by MGI or its Affiliates; (h) misuse of the Know how received hereunder by MGI or its agents; (i) failure of any Products supplied hereunder to comply with the applicable approved specifications in the event that such non compliance (1) could have been detected by MGI carrying out visual inspection on the supplied Products with ordinary diligence or (2) results from any Products which has been altered, changed, packed or re-packed, processed or otherwise treated other than in strict accordance with HHC's instructions and specifications; or (j) any negligent or wrongful act or omission and/or any breach by MGI or by any of its local distributors and/or Affiliates of any of MGI's obligations, representations and/or warranties hereunder.

11.2 HHC shall be liable for and shall defend, indemnify and bold MGI and its Affiliates, officers, directors and employees free and harmless from and against any and all liabilities, damages, losses, costs, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgements or administrative and judicial orders, but in no event in excess of the sums already paid by MGI under Article 7 hereabove, arising out of or in any way resulting from any claim, suit or proceeding to the extent arising out of or resulting from (a) a claim that the use of the Know-

how and the Patent infringes any intellectual property right of any third party (but only to the extent HHC is covered by Syntex in this regard pursuant to the applicable provisions of the Syntex Agreement); (b) any failure by HHC or its Affiliates to comply with any applicable laws, regulations and/or administrative decision regarding the Registration and/or the Products; (c) the performance by HHC or its agents of any development activities relating to the Products, as described at Article 4.2 above; (d) any defect in the results of the development work carried out by or on behalf of HHC as provided at Article 4.2 above; (e) the storage, distribution, sampling, record-keeping, analysis, transfer or sale of the Products by laic or its agents; (f) the promotion, advertising and marketing of the Products by HHC or its Affiliates; (g) misuse of the Know-how by HHC or its Affiliates; or (h) any negligent or wrongful act or omission and/or breach by HHC or its Affiliates of any of its obligations and/or warranties hereunder.

11.3 Being understood that each of the Parties hereto shall take all reasonable steps to avoid or mitigate any loss, damage or liability which might give rise to a claim under this Agreement, a Party seeking indemnification pursuant to this Article 11 (an "Indemnified Party) shall give prompt and full written notice to the Party from whom such indemnification is sought (the "Indemnifying Party") of the assertion of any claim, or the commencement of any action, suit or proceeding in respect of which indemnity is or may be sought hereunder, provided however that no failure to give such notice or co-operation shall relieve the Indemnifying Party of any liability and/or obligation hereunder (except to the extent the Indemnifying Party has suffered actual prejudice thereby). The Indemnifying Party shall have the sole right to control

the defense and settlement thereof. The Indemnified Party will give the Indemnifying Party such information with respect thereto as the Indemnifying Party may reasonably request and will co-operate with the Indemnifying Party in the defense of said claim, suit or proceeding as the Indemnifying Party may reasonably request The Indemnified Party shall not, except at its own cost, voluntarily make any payment or incur any expense with respect to any claim, suit or proceeding without the prior written consent of the Indemnifying Party.

In addition, the Indemnifying Party shall be subrogated to the rights of the Indemnified Party against any third party, and such Indemnified Party hereby assigns to the Indemnifying Party all claims, causes of action and other rights which the Indemnified Party may then have against any third party, including Affiliates and, in the case of HHC, against any contract manufacturer of the Products, with respect to the claim, suit or proceeding which is the subject of the claim for indemnification hereunder. Conversely, and without in any way limiting the obligation of either Party to indemnify the other Party as herein provided, to the extent that either Party shall fail to perform its indemnification obligations under this Article 11, such Party owing a duty of indemnification hereby assigns to the other Party all claims, cause of action and other rights which the Party owing such duty may then have against any third party, including Affiliates and, in the case of HHC, against any contract manufacturer of the Products, with respect to the claim, suit or proceeding.

It is understood and agreed that the operation and application of this Article 11.3 are however subject to any right of Syntex (USA.) Inc. under articles 8.3, 8.4

and 8.5 of the Syntex Agreement, which are hereby acknowledged and accepted by MGI.

11.4 MGI shall be solely responsible towards its customers for handling all matters concerning the Products subject to cooperation with HHC on any recall or other regulatory matters that may be injurious to HHC. MGI shall be responsible for any expired Products, whether stored by MGI and/or its local distributors or returned by wholesalers, pharmacists, doctors, hospitals to whom said Products have been sold. MGI shall indemnify, defend and hold HHC and its Affiliates, directors, officers and employees wholly free and harmless from and against any and all liabilities, damages, losses, costs, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgements or administrative and judicial orders arising therefrom; except with respect to any recall or other regulatory action arising from any breach by HHC or its Affiliates of any warranty, representation or other material obligation contained in this Agreement or the negligence or willful misconduct of HHC or its Affiliates.

11.5 Each Party shall indemnify and hold the other Party wholly harmless from and against any and all liabilities, damages, losses, costs, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgements or administrative and judicial orders arising out of any behavior contrary or in excess to the provisions of Article 18.1 hereunder.

11.6 THE SOLE REPRESENTATIONS AND WARRANTIES THAT ABC MAKES WITH RESPECT TO THE MATTER CONTEMPLATED BY THIS AGREEMENT ARE EXPRESSLY SET FORTH IN

ARTICLE 10.1. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, HHC MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, OF MARKETABILITY, CAPACITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE KNOW-HOW, THE PATENTS AND/OR THE PRODUCTS. NO ORAL OR WRIT TEN REPRESENTATION BY OR ON BEHALF OF HHC SHALL BE INTERPRETED TO CONTAIN ANY SUCH WARRANTY. NEITHER MGI NOR ANY OF ITS EMPLOYEES OR REPRESENTATIVES IS AUTHORISED TO GIVE ANY WARRANTIES OR MAKE ANY REPRESENTATION ON BEHALF OF HHC.

11.7 THE SOLE REPRESENTATIONS AND WARRANTIES THAT MGI MAKES WITH RESPECT TO THE MATTER CONTEMPLATED BY THIS AGREEMENT ARE EXPRESSLY SET FORTH IN ARTICLE 10.2 AND MGI HEREBY DISCLAIMS ALL OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED. NO ORAL OR WRITTEN REPRESENTATION BY OR ON BEHAIF OF MGI SHALL BE INTERPRETED TO CONTAIN ANY SUCH WARRANTY. NEITHER HHC NOR ANY OF ITS EMPLOYEES OR REPRESENTATIVES IS AUTHORISED TO GIVE ANY WARRANTIES OR MAKE ANY REPRESENTATION ON BEHALF OF MGI.

11.8 NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, NEITHER OF THE PARTIES SHALL BE LIABLE TOWARDS THE OTHER FOR INDIRECT, SPECIAL, PUNITIVE, EXEMPLARY, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION LOSS OF PROFITS OR REVENUES,

REGARDLESS OF WHETHER SUCH DAMAGES WERE FORESEEABLE OR NOT. THIS CLAUSE WILL HOWEVER NOT BE APPLICABLE IN CASE OF BREACH BY MGI OF THE LIMITATIONS OF GRANTS AND THE NON-COMPETITION OBLIGATIONS STATED AT ARTICLE 2 AND BREACH BY EITHER PARTY OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS STATED AT ARTICLE 14 OF THIS AGREEMENT.

11.9 Each Party agrees to procure and maintain in full force and effect during the term of this Agreement valid and collectible insurance policies in connection with its activities as contemplated herein. In particular, MGI at its own cost shall cause HHC and their respective employees, officers, directors and contractors to be added as additional named insured throughout the term of this Agreement on all policies of general commercial liability insurance and product liability insurance covering MGI, which coverage shall, when MGI either initiates clinical trials on the Products or begins marketing or distributing the Products for commercial sale or for promotional purposes, have limits of liability which are commercially reasonable in the Territory but shall be not less than USD 30,000,000 (United States Dollars thirty million) per loss occurrence. Within 5 (five) days of the Effective Date and of each beginning of each policy period, MGI shall provide HHC with a certificate evidencing the coverage required hereby and the amount thereof. Such coverage shall be with a reputable insurance company having at least an A.M. Best "A" rating and shall have to be maintained for not less than 6 (six) years following expiration or termination of this Agreement for any reason or if such coverage is of the "claims made" type, for ten years

following expiration or termination of this Agreement for any reason.

ARTICLE 12 - THE PATENTS

12.1 MGI agrees that any Products distributed, promoted, marketed and sold by it will be marked with a notice of patent rights as necessary or desirable under applicable law to enable the Patent to be enforced to the maximum degree.

12.2 MGI shall cooperate with HHC as may be reasonably requested by HHC and at HHC's expense for the purpose of filing for and obtaining patent extensions and supplementary or complementary protection certificates, if available, of the Patents under the relevant applicable laws of each country of the Territory.

12.3 HHC hereby undertakes that it shall use commercially reasonable efforts to cause Syntex to comply with its obligations under the Syntex Agreement with regard to maintenance, defense and enforcement of the Patents in the Territory. In the event that Syntex fails to maintain, defend and enforce such Patents, then HHC shall use commercially reasonable efforts do so, to the fullest extern permissible under the relevant provisions of the Syntex Agreement.

12.4 MGI shall promptly inform HHC in writing upon its becoming aware of any possible third party infringement of the Patents. HHC shall thereafter promptly report the case to Syntex in accordance with the relevant provisions of the Syntex Agreement, for appropriate action by Syntex and/or HHC. MGI shall provide assistance, bearing exclusively its own costs, as may be reasonably requested by HHC.

12.5 MGI shall promptly inform HHC in writing upon its becoming aware of any notice or claim that the distribution, promotion, marketing and sale of the Product in the Territory for the Field in accordance with the terms and conditions of this Agreement infringe any third party's patent rights, or in the event of the commencement of any suit or action for infringement of any such third party's rights. HHC shall therefore promptly report the case to Syntex in accordance with the relevant provisions of the Syntex Agreement, for appropriate action. MGI shall not settle or compromise any such suit or action without the prior written consent of HHC and shall provide assistance, bearing exclusively its own internal costs, as may be reasonably requested by HHC.

12.6 MGI shall fully co-operate with HHC in connection with any action or proceeding relating to the validity of the Patent, including if required being joined as a necessary party to such action or proceeding at HHC's expense.

ARTICLE 13 - THE SYNTEX AGREEMENT

13.1 MGI acknowledges and understands that the rights granted to it by HHC in this Agreement derive from the Syntex Agreement and are subject to the terms thereof, a copy of which with economic terms redacted MGI has reviewed. The Parties hereby acknowledge and agree that in case of any discrepancy or conflict between this Agreement and the Syntex Agreement, this Agreement shall be construed in a manner consistent with the Syntex Agreement, except for those obligations of HHC towards Syntex which do not have a material impact on MGI's obligations hereunder.

13.2 During the term of this Agreement, HHC agrees to comply in all material respects with its obligations under the Syntex Agreement to the extent necessary to preserve its rights in the Territory thereunder, except to the extent that such compliance is dependent upon MGI.

13.3 During the term of this Agreement, MGI agrees to act in compliance with the Syntex Agreement to the extent required by the Syntex Agreement, including without limitation any confidentiality restrictions contained therein.

13.4 MGI acknowledges and agrees that HHC has acquired certain rights in and to the Compound pursuant to the Syntex Agreement and that any and all rights that MGI is acquiring pursuant to this Agreement arc subject to, in all cases, the Syntex Agreement. Further, MGI acknowledges that under certain circumstances, Syntex has the right to terminate certain of HHC's rights under the Syntex Agreement. HHC shall promptly provide MGI with a copy of any notice of termination it may receive from Syntex under the Syntex Agreement and the Parties shall thereafter discuss in good faith appropriate steps to cure such termination event.

ARTICLE 14 - CONFIDENTIALITY

14.1 MGI shall treat as strictly confidential, and shall use solely for the purpose of and in accordance with this Agreement, the Know-how, Improvements and/or any information and/or document received hereunder or in connection with the Contemplated Transaction not generally known to the trade, including but not limited to non-public information relating to the Patent as well as the results of the development work performed hereunder (all hereinafter referred to

as the "Confidential Information"). MGI shall not make such Confidential Information available to any third Party, including any of its Affiliates, except to competent government agencies to which it will be necessary to disclose such Information, and in this case (a) strictly to the extent requested by said agencies and (b) only upon exercise of its best efforts to cause said agencies to maintain confidentiality thereof.

14.2 Such Confidential Information shall only be made available to such employees of MGI who are directly and necessarily involved in the authorized use of Confidential Information and who are subject to a secrecy obligation by contract, to the extent strictly necessary to perform their duties and obligations hereunder.

14.3 Notwithstanding expiration or termination of this Agreement for any reason, these confidentiality and non-use obligations shall continue until the Confidential Information has become generally known to the public, provided however that nothing contained herein shall in any way restrict or impair the right of MGI to use, disclose or otherwise deal with Information which MGI can demonstrate to HHC by clearly convincing documentation:

14.3.1 is or hereafter becomes part of the public domain through no act or omission of MGI, its employees, Affiliates and/or local distributors, or

14.3.2 MGI was in lawful possession of prior to receipt of the Confidential Information from HHC, or

14.3.3 previously was, or at any time hereafter is, received in good faith by MGI from sources other than HHC and which did not originate, directly or indirectly, from Syntex, or

14.3.4 at the time of disclosure., was known by MGI or an Affiliate or local distributor, or after disclosure was independently developed by MGI, an Affiliate or local distributor without use of the Confidential Information.

14.4 Prior to the publication or presentation of any information or data arising from the activities described at Article 5.3 above, MGI shall submit to HHC a summary of the proposed publication or presentation prior to the submission thereof for publication or presentation. The purposes for such prior submission are: (i) to provide HHC with the opportunity to review and comment on the contents of the proposed publication or presentation, (ii) to identify any Confidential Information to be deleted from the proposed publication or presentation, and (iii) to agree in good faith on the contents and timing of such proposed publication or presentation.

14.5 HHC shall keep strictly confidential, in the same way mutatis mutandis as provided here above for MGI in respect of Confidential Information, any MGI Confidential Information (as defined herein) received from MGI hereunder, except as otherwise specifically provided in this Agreement. As used herein, the term "Confidential Information" shall mean all information disclosed by MGI to HHC, relating to the markets, customers, suppliers, patents or patent applications, inventions, know-how, data or information, products, research and development, procedures, designs, formulas, business plans, financial projections, employees, consultants or any other similar aspects MGI's present or future business, whether such information is disclosed in written, oral, electronic, graphic or other format.

ARTICLE 15 - FORCE MAJEURE

15.1 If the performance of this Agreement is prevented or restricted by government action, war, fire, explosion, flood, strike, lockout, embargo, act of God, or any other similar cause beyond the control of the defaulting Party, the Party so affected shall be released for the duration of the force majeure, or such other period agreed between the Panics as being reasonable in all circumstances, from its contractual obligations directly affected by the force majeure, provided that the Party concerned shall:

15.1.1 give prompt notice in writing to the other Party of the cause of force majeure;

15.1.2 use commercially reasonable efforts to avoid or remove such cause of non-performance;

15.1.3 continue the full performance of this Agreement as soon as such cause is removed.

15.2 The Parties shall take all reasonable steps to minimize the effects of force majeure on the performance of this Agreement and shall, if necessary, agree on appropriate measures to be taken. Should the force majeure continue for more than 6 (six) months, then the other Party shall have the right to terminate this Agreement forthwith.

15.3 Notwithstanding anything contained in this Article 15, obligations to pay money accruing prior to the force majeure event are never excused by force majeure.

ARTICLE 16 - TERM

16.1 This Agreement comes into force at the Effective Date hereof. Unless terminated earlier pursuant to the provisions hereof and subject to the validity of the Syntex Agreement, it shall remain in force for a

period of .10 (ten) years from the date of launching by MGI of the first of the Products and, unless either of the Parties gives notice of termination to the other Party in writing 6 (six) months before the termination of the initial or of any extension period, it shall be automatically renewed for periods of 3 (three) years.

ARTICLE 17 - TERMINATTON

17.1 Each of the Parties reserves the right to terminate this Agreement in case of any substantial or persistent breach of any of the terms and conditions of this Agreement by the other Party, including, without limitation, as provided at Articles 2.12 and 7.3.6 above. The defaulting Party shall be given in writing a 60 (sixty)-day period, except as otherwise specifically provided, to fulfil its obligations hereunder and, if after such period it is still in breach of the Agreement, the other Party shall have the right to terminate this Agreement by written notice to the defaulting Party. In addition, MGI hereby acknowledges and agrees that HHC shall be entitled to terminate this Agreement by written notice to MGI in case of termination of any agreement between MGI and any third party for the supply of Products to MGI as per Article 2.5 above due to a breach by MGI.

17.2 Either Party shall have the right to terminate this Agreement upon written notice to the other Party, if such Party shall become insolvent or shall make an assignment for the benefit of creditors or become involved in receivership, bankruptcy or other insolvency or debtor relief proceedings, or any similar proceedings, or in proceedings, voluntary or forced, whereby the Party involved is limited in the free and unrestrained exercise of its own judgement as to the carrying out of the terms of this Agreement. The Parties intend that upon HHC's termination of this

Agreement pursuant to this Article 17.2, all rights granted hereunder to MGI shall be terminated and revert to HHC. The Patties acknowledge and agree that all rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Article 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(52) of the Bankruptcy Code, and that MGI, as a licensee hereunder, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

17.3 In case the ownership or control (as this tents is defined at Article 1.2 here above) of MGI or of a legal entity directly or indirectly owning or controlling MGI changes (whether by merger, consolidation, reorganization, take over, change in the ownership of the share capital or otherwise), details of any such change in ownership or control shall he notified in writing by MGI to HHC as soon as possible and in any case no later than 5 (five) days of its occurrence. HHC shall then have the right to terminate this Agreement by giving MGI or the new entity owning or controlling MGI 30 (thirty) days advance notice in writing if (i) the entity owning or controlling MGI has in its portfolio a product competing with the Products (as defined at Article 2.4 here above) and/or (ii) MGI's commitments and investments on the Products in terms of promotion and marketing efforts, sales force activities, sales performance etc. arc not maintained by said new entity.

17.4 If MGI does not achieve the annual minimum of sales as referred in Articles 7.3.6 and 8.7 hereabove (e.g., eighty-five percent (85%) of MGI's Unit Sales base forecast) in any country(ies) of the Territory in a given year starting from the second year from launch,

the Parties shall meet not later than February 28th of the following year to (a) discuss the market for the Products, the competitive environment and MGI's sales and marketing activities, plans and resources for the Products and (b) agree on a remedial plan to be implemented by MGI in such country(ies). MGI shall thereafter have a period of one hundred twenty (120) days to implement such remedial plan and if it fails to do so, HHC will have the right to terminate this Agreement with respect to the country or countries in which MGI failed to implement such plan upon thirty (30) days written notice to MGI.

17.5 HHC shall have the right to terminate this Agreement by written notice to MGI if MGI fails to launch the Products as provided in Article 8 hereabove, or if MGI or any of its agents, employees, Affiliates or distributors breaches the confidentiality and/or non use obligations provided for in Article 14 hereabove. MGI shall have the right to terminate this Agreement by written notice to HHC if HHC or any of its agents, employees or Affiliates breaches the confidentiality and/or non use obligations provided for in Article 14.5 hereabove.

17.6 Without limiting the generality of the foregoing, termination or expiration of this Agreement for any reason shall not extinguish any existing claims either of the Parties may have for indemnification and shall not preclude either of the Parties from pursuing any claim for indemnification such Party otherwise may have to the extent that the circumstances giving rise to such claim arose prior to, on or after the date of termination or expiration

17.7 Upon expiration or termination of this Agreement for any reason. MGI shall:

17.7.1 subject to Article 17.7.4 hereunder, promptly cease any use and/or exploitation of the Registration;

17.7.2 subject to Article 17.7.4 hereunder, promptly cease any use of the Trademark and not hold itself out as a distributor of the Products;

17.7.3 subject to Article 17.7.4 hereunder, promptly terminate using the Know-how, the Improvements and the results of the development work carried out in accordance with Article 5.3 hereunder and return or deliver all such materials to HHC without retaining copies, notes, summaries or translations thereof;

17.7.4 promptly terminate distributing, promoting, marketing and selling the Products onto the market, provided that it shall have a three-month period to sell its existing stock of Products, subject to payment of royalties hereunder. Any stock remaining at the expiry of said three months period shall be destroyed by MGI at MGI's expenses, unless otherwise directed by HHC.

17.8 Unless otherwise set forth herein, the Parties' remedies under this Agreement are intended to be cumulative and not mutually exclusive.

ARTICLE 18 - MISCELLANEOUS

18.1 Independent contractor status

The status of HHC and MGI under the business arrangement established by this Agreement is that of independent contractors. MGI shall perform as an independent contractor in relation to both HHC and MGI's customers and, accordingly, MGI shall

purchase the Products from HHC or HHC's nominee and resell them to its customers in its own name and for its own account. With the sole exception of the provisions of Article 4.5 here above regarding Mars role as HHC's FDA Agent, MGI has no authority whatsoever to act as an agent or representative of HHC nor any authority or power to contract in the name of or create any liability against or otherwise bind HHC in any way for any purpose, nor shall HHC have such authority or power to so bind MGI.

18.2 Notices

All reports, notices and communications given or made pursuant to this Agreement by one Party to the other shall be validly given or made for all purposes, in the absence of acknowledgement of receipt, on the date of mailing if mailed by registered airmail or by international courier to the addressee Party at the following addresses, respectively:

HELSINN HEALTHCARE SA
P.O. BOX 357
6915 Pambio-Noranco
SWITZERLAND;
For the attention of the Legal Department

MGI PHARMA INC.
6300 West Old Shakopee Road
Suite 110
Bloomington, MN 55438-2318
USA
For the attention of Manager, Legal Affairs

with a copy to:

Dorsey & Whitney LLP
220 5. 6th Street
Minneapolis, MN 55402
Attention: Timothy S. Hearn

18.3 Binding Effect. Subject to the provisions of articles 2.1, 2.8 and 18.6 herein, this Agreement shall inure to the benefit of, and be binding upon, the respective successors of the Parties.

18.4 Waiver. The failure of a Party to insist upon strict performance of any of the terms and conditions of this Agreement by the other Party shall not constitute a waiver of any of the provisions hereof and no waiver by a Party of any of said terms and conditions shall be deemed to have been made unless expressed in writing and signed by such waiving Party.

18.5 Interpretation.

18.5.1 The language of this Agreement is English. No translation into any other language shall be taken into account in the interpretation of the Agreement itself.

18.1.2 The headings m this Agreement are inserted for convenience only and shall not affect its construction.

18.5.3 Where appropriate, the terms defined in Article 1 hereabove and denoting a singular number only shall include the plural and vice versa.

18.5.4 References to any law, regulation, statute or statutory provision includes a reference to the law, regulation, statute or statutory provision as from time to time amended, extended or re-enacted.

18.6 Assignment. This Agreement and the licenses and other rights conferred upon MGI under this Agreement are personal to MGI and cannot be transferred, sublicensed, assigned or otherwise disposed of (by operation of law or otherwise) by MGI without the prior, written authorization of HHC, which authorization shall not be unreasonably withheld; provided,

however, that MGI shall be entitled to assign this Agreement without such consent in connection with a merger, acquisition or sale of substantially all of its assets or to any of its Affiliates, in accordance however with the criteria established at Article 17.3 hereabove HHC shall have the right to assign or transfer, in whole or in part, this Agreement to any of its Affiliates.

18.7 Statements to the Public. Neither HHC nor MGI shall make or procure or permit the making of any announcement or statement to the public with respect to this Agreement, its subject matter or any ancillary matter without the prior consent of the other Party, which consent shall not be unreasonably withheld.

The wording and the timing of any press release or of any other announcement and/or statement to the public shall have to be agreed upon in advance between the Parties.

Nothing herein shalt prohibit MGI from disclosing information to the extent required by the U.S. Securities and Exchange Commission, Nasdaq or other similar authorities. It is however understood and agreed that (a) the contents of any copy of this Agreement, or of any other agreement between the Parties, which has to be sent to the SEC shall have to be previously agreed upon between the Parties and shall be in redacted form to maintain the confidentiality of proprietary and/or competitivity sensitive information, and (b) MGI shall use its best efforts to obtain authorization by the SEC to keep confidential any information which is deemed to be confidential by the Parties or any of them or which may, in either Party's opinion, put a competitive advantage to third parties.

18.8 Expenses. Unless specifically and expressly provided for to the contrary in this Agreement, each of the Parties shall bear its own expenses incurred in connection with the performance of this Agreement.

18.9 Survival. The following provisions shall survive expiration or termination of this Agreement for any reason: Articles I (whole clause), 3.4, 4.2 (last sentence), 4.7 (last sentence), 9.1, 11 (whole clause), 14 (whole clause), 17.6 through I7.8, 18 (whole clause), 20 (whole clause) and 21 (whole clause).

ARTICLE 19 - APPENDICES

19.1 The following Appendices shall he an integral part of this Agreement:

Appendix 1: List of Know-how Items

Appendix 2: Patents

Appendix 3: Products

Appendix 4: Development Chart

Appendix 5: Post-Registration Regulatory Activities

Appendix 6: Adverse Events Reporting

Appendix 7: Products Recall Procedure

Appendix 8: Escrow Agreement

Appendix 9: MGI's unit sales base forecast - Annual Minimum Sales

Appendix 10: Promotion and Marketing Activities

ARTICLE 20 - LAW TO GOVERN AND ARBITRATION

20.1 This Agreement shall be governed by and construed in accordance with the law of Switzerland.

20.2 It is the express decision of the Parties that any dispute which may arise between the Parties concerning this Agreement, which cannot be settled amicably, shall be submitted to arbitration for final decision. Also, any dispute as to the applicability of the arbitration clause shall he subject to arbitration.

Notwithstanding the above, each Party expressly reserves the right to seek judicial relief from a court of competent jurisdiction if the other Party is or appears to be in violation of such other Party's obligations of non-use and non-disclosure under Article 14 above, including, without limitation, any injunction or other preliminary relief.

20.3 It is expressly agreed that arbitration shall be held in English language in Geneva (Switzerland), and conducted under the Rules of Arbitration of the International Chamber of Commerce. The court of arbitration shall consist of three arbitrators. Each Party is entitled to nominate one arbitrator. If, within one month after receipt of the request for arbitration filed by one Party, the other has not yet appointed an arbitrator, such arbitrator shall be appointed by the International Court of Arbitration of the International Chamber of Commerce on request of the first Party, The two arbitrators shall nominate the president of the court of arbitration, who shall be a lawyer qualified to practice and currently practicing as an attorney-at-law or as a judge. If they cannot come to terms within one month, the president of the court of arbitration shall be nominated by the International Court of Arbitration of the International Chamber of Commerce, on request of the more diligent Party.

20.4 If one of the arbitrators is unable to fulfil his/her duties for any reason the Party having nominated him/her shall nominate another arbitrator

within one month, otherwise this arbitrator will be nominated by the International Court of Arbitration of the International Chamber of Commerce.

20.5 If the arbitrators or the president have to be replaced, the proceedings do riot have to he started anew and will continue at the point where they were stopped.

20.6 The court of arbitration is hereby expressly instructed to act with most diligence and to keep any term as short as possible and to render the decision as soon as possible.

20.7 The Parties hereby stipulate that any arbitration hereunder shall be subject to the following rules: (a) the arbitrators may not award or assess punitive damages against either Party; and (b) each Party shall bear its own costs and expenses of the arbitration and one-half (112) of the fees and costs of the arbitrators, subject to the power of the arbitrators, in their sole discretion, to award all such reasonable Costs, expenses and fees to the prevailing Party.

20.8 The Parties agree that the arbitrator's award shall be the sole and exclusive remedy between them regarding any claims, counter-claims, issues or accountings presented or pled to the arbitrator and that any costs, fees or taxes incident to enforcing the award shall be, to the maximum extent permitted by law, charged against the Party resisting such enforcement.

20.9 Notwithstanding the foregoing, any Party may bring a case of action against the other Party before any court of competent jurisdiction at the domicile of the defendant Party, if and to extent that any arbitral award rendered in the arbitration proceedings is unenforceable.

20.10 Subject to the provisions of Article 20.9, in the event that an award is rendered pursuant to this Article 20 by an arbitrator in favor of HHC, the Parties acknowledge and agree that such award shall be enforceable by HHC. and MGI hereby consents to the exclusive jurisdiction for purposes of enforcement of any such award against MGI to the United States District Court for the District of Delaware, or, if jurisdiction or venue cannot be laid therein, the jurisdiction of any courts in the Stale of Delaware. Each of the Parties hereby consents to the exclusive jurisdiction of such courts (and of the appropriate appellate courts) for the purposes set forth above.

ARTICLE 21 - ENTIRETY OF AGREEMENT AND SEVERABILITY

21.1 This Agreement supersedes all prior agreements and understandings, whether oral or written, made by either Party or between the Parties and constitutes the entire agreement of the Parties with regard to the subject matter hereof. This Agreement shall not be considered extended, cancelled or amended in any respect unless done so in writing and signed on behalf of the Parties hereto.

21.2 The Patties hereby expressly state that it is the intention of neither Party to violate any rule, law and regulations. If any provision of this Agreement is rendered invalid or unenforceable, the Parties agree to renegotiate such provision in good faith and to replace it with valid and enforceable provisions in such a way as to reflect as nearly as possible the intent and purpose of the original provision.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate by their duly authorized officers.

For and on behalf of
HELSINKI HEALTHCARE SA

/s/ Ricardo Braglia
Ricardo Braglia
Managing Director

/s/ Enrico Braglia
Enrico Braglia
Managing Director

For and on behalf of
MGI PHARMA, INC.

/s/ Charles N. Blitzer
Charles N. Blitzer
President and Chief Executive Officer

/s/ Leon O. Moulder, Jr.
Leon O. Moulder, Jr.
Executive Vice President

LEGAL REVIEW AND APPROVAL

FIRST APPENDIX

To an Agreement between HEISINN HEALTHCARE SA and MGI PHARMA INC. dated April 6th 2001

LIST OF KNOW-HOW ITEMS

See enclosed documents

Chemistry, Manufacturing and Controls Know-how

The CMC Know-how on the Compound is included in the IND 39,797 and the relative correspondence with FDA up to February 28, 2001.

Pre-clinical Know-how

The Pre-clinical Know-how on the Compound is described in the following list and it includes all final reports available up to February 28, 2001.

Note: Studies coded "PALO - ## - ##" are sponsored by HHC.

Pre-clinical studies

Receptor Binding, Cardiovascular, Respiratory and Renal Activity

AT 6032
E.H.F. Wong
The receptor binding profile of RS-25259-197 at 5HT, and other receptors using radioligand binding techniques

AT 6036
K Leung
Activity of RS-25259-197 at 5-HT receptors in isolated tissues

AT 6373
E. Leung
Activity of RS-25259-197 at 5-HT, receptors in guinea pig ileum

AT 6976
E. Leung
Effect of RS-25259-197 at 5-HT, receptors, in vitro

CL 6721
D.W. Bonhaus and D.N. Lowy
Saturation, competition and kinetic analysis of [^{3}H]-RS-25259-197 binding

AT 6325
L. B. Jakeman
Distribution of [^{3}H] RS-25259-197 binding sites in rat and mouse brain by quantitative autoradiography

AT 5964
R. Alvarez
Effect of RS-25259-197 on 5-HT, receptors positively coupled to adenylate cyclase in guinea pig hippocampal membranes

AT 6446
L. A. Perkins
The effect of RS-25259-197 at 5-HT, receptors and on substance P in vitro

AT 5618
C.H. Lee
The effects of intravenous administration of RS-25259-197 on the bradycardic response to 2-methyl-5-hydroxytryptamine in anesthetized rats

AT 5763
C.H. Lee
The effects of intra-duodenal administration of RS-25259-197 on the bradycardic response to 2-methyl-5-hydroxytryptamine in anesthetized rats

AT 5389
C.H. Lee
The effects of topical application of RS 25259-197 on the bradycardic response to 2-methyl-5-hydroxytryptarnine in anesthetized rats

AT 5484
C.H. Lee
The effects of topical application of an aqueous solution of RS-25259-197 on the bradycardic response to 2-methyl-5-hydroxytryptaminc in anesthetized rats

AT 5491
C.H. Lee
The effects of topical application of RS-25259-197 on the bradycardic response to 2-methyl-5-hydroxytryptarnine in anesthetized cats

AT 5493
L.D. Wood and L.G. Johnson
Hemodynamic effects of 1S-25259-197 and ondansetron administered intravenously to anaesthetized dogs

AT 6242
C.Calder
The effect of RS-25259-197 on intra-atrial, intraventricular and atrioventricular conduction in the anaesthetized dog

PALO-99-48
A.I. El Amrani
Palonosetron, RS-17825-007 and RS-42358-197: evaluation of effect on cardiac action potential in isolated canine Purkinje fibres

PALO-99-49
E.Martel
Palonosetron evaluation of effects on blood pressure, heart rate and electrocardiogram after single intravenous dosing in conscious dogs of both sexes

PALO-00-10
K.Lansdell
Effect of Palonosetron on HERG currents recorded from stably transfected HEK 293 cells

AT 6168
L.G. Johnson
Interaction of RS-25259-197 with autonomic agents in anesthetized dogs

AT 6161
D. Martin and P. Hicks
Effect of RS-25259-197 on respiratory function and blood pressure in anesthetized dogs

AT 6005
K.D. Lake
The effect of RS-25259-197 on renal function in conscious, saline-loaded rats

Principal Activity and Pharmacology Auxiliary Studies

AT 6929
M.L. Turke
Effect of intravenously administered RS-25259-197 and ondansetron on cisplatin-induced emesis in dogs

AT 6030
M.L. Turke
Effect of RS-25259-197 and ondansetron on ducarbazine-indueed emesis in dogs

AT 6002
M.L. Turke
Effect of RS-25259-197 and ondansetron on mechlorethamine-induced emesis in dogs

AT 6001
M.L. Turke
Effect of RS-25259-197 and ondansetron on actinomycin D-induced emesis in dogs

AT 6003
M.L. Turke
Duration of action of intravenously administered RS-25259-197 and ondansetron on cisplatin-induced emesis in dogs

AT 6033
J.I. Gianettoni
Duration of action of intravenously administered RS-25259-197 on cisplatin-induced emesis in dogs

AT 6027
M.L. Turke
Therapeutic effect of intravenously administered RS-25259-197 and ondansetron on cisplatin-induced emesis in dogs

AT 6028
M.L. Turke
Effect of orally administered RS-25259-197 and ondansetron on cisplatin-induced emesis in dogs

AT 6313
J.I. Gianettoni
Correlation of anti-emetic activity and plasma levels of RS-25259-197 in cancer chemotherapy treated dogs

AT 5531
M.L. Turke
Effect of RS-25259-197 and ondansetron on cyclophosphamide-induced emesis in dogs

AT 6004
J.I. Gianettoni
Effect of RS-25259-197, ondansetron and granisetron on protoveratrine A-induced emesis in dogs
Comment: study invalidated

AT 6035
J.I. Gianettoni
Effect of RS-25259-197, ondansetron, and granisetron on copper sulfate-induced emesis in dogs

AT 6034
J.I. Gianettoni
Effect of RS-25259-197, ondansetron, and granisetron on apomorphine-induced emesis in dogs

AT 6664
M. R. Perry
Effect of intravenously administered M-25259-197 on cisplatin-induced emesis in ferrets

AT 5999
M.R. Perry
Effect of orally administered RS-25259-197 on cisplatin-induced emesis in ferrets

AT 6031
M.R.Perry
Duration of effect of orally administered RS-25259-197 on cisplatin-induced emesis in ferrets

AT 5244
M.L. Turke
Effect of RS-25259-197 on gastric emptying of a test meal in rats

AT 5985
J.L. Nunes
The effect of RS-25259-197 on the gross behavior of mice

AT 5452
C. Ward
The effects of RS-25259-197 on feeding behavior

AT 6037
E. Wong
An assessment of the actions of RS-25259-197 on mouse behavior in the black: white test box

PALO-99-11
C.N. Williams
Palonosetron hydrochloride: assessment of proconvulsant activity in mice following oral administration

AT 6777
W. R. Waud and J.D. Prejean
In vivo combination chemotherapy evaluation of RS-25259 HCI and cisplatin against murine P388 Leukemia

ADME

AT 6303
P. Weller et al.
Pharmacokinetics of RS-25259-007 after single oral doses of RS-25259-197 administered to male rats

AT 6304
P. Weller et al.
Pharmacokinetics of RS-25259-007 after single oral doses of RS-25259-197 administered to dogs

AT 6302
P. Weller et al.
Pharmacokinetics of RS-25259-007 and its N-oxide metabolite following once daily oral doses of RS-25259-197 administered to male rats over five days

AT 6301
P. Weller et al.
Plasma pharmacokinetics of RS-25259-007 and its N-oxide metabolite following once daily oral doses of RS-25259-197 administered to female dogs over five days

AT 5975
P. Weller et al.
Metabolic disposition and tissue distribution of [14C]-RS-25259-l97 after a single intravenous dose to rats

AT 6264
P. Weller et al.
Metabolic disposition following single intravenous and oral doses of [14C]-RS25259.197 and tissue

distribution after a single intravenous dose of [14C]-RS-25259197 to rats

AT 6285
P. Weller and M. Young
Metabolic disposition and tissue distribution to brain, eye and intestines after a single intravenous dose of [14C]-RS-25259-197 to pigmented rats

AT 5976
P. Weller et al.
Metabolic disposition of [14C]-RS-25259-197 after single intravenous and oral doses to dogs

DM 1078
P. Weller et al.
Metabolic disposition of [14C]-RS-25259-197 after single intravenous and oral doses administered to Cynomolgus monkeys
Comment: Draft report available (no further finalization performed by Syntex)

CL 6204
L. Brown and O. Weller
Binding of RS-25259-197 to plasma protein in vitro

PALO-00-02

Identification of M4

Step 1:

S. Madden

Investigation of [14C]-Palonosetron Metabolism in Human Hepatic Microsomes

Step 2:

G. McCorquodale

Investigation to Assess for the Presence and Structural Equivalence of Metabolic M4 in human

Urine Versus That formed by Incubation of [14C]-Palonosetron with Human Hepatic Microsomes

Toxicology Studies

Acute Toxicology

AT 5921
A. J. Sonderfan
Acute intravenous toxicity study in mice with RS-25259-197

AT 5939
A. J. Sonderfan
Acute intravenous toxicity study in rats with RS-25259-197

AT 5922
A. J. Souderton
Acute intravenous toxicity study in dogs with RS-25259-197

AT 6284
F.D. Andrew
Acute oral toxicity study in rats with R5-25259-197

AT 6268
F.D. Andrew
Acute oral toxicity study in Beagle dogs with RS-25259-197

Repeated-dose Toxicology

AT 5962
A. J. Sonderfan
Intravenous 1-month toxicity study in rats with RS-25259-197

PALO-99-19
C. Green
Palonosetron hydrochloride: intravenous administration tolerance study in the dog

AT 5963
A. J. Sonderfan
Intravenous 1-month toxicity study in dogs with RS-2.5259-197

AT 6329
F.D. Andrew
One-month oral toxicity study in rats with RS-25259-197

AT 6328
F.D. Andrew
One-month oral toxicity study in Beagle dogs with RS-25259-197

Subchronic Toxicology

AT 6665
A.J. Sonderfan
Oral three-month toxicity study with RS-25259-007 in rats

AT 6751
A.J. Sonderfan
Three-month oral dose-ranging study of RS-25259-197 in mice

AT 6787
A.J. Sonderfan
Oral three-month toxicity study with RS-25259-007 in dogs

Chronic Toxicology

PALO-99-08
T. Smith
Palonosetron hydrochloride: 26 week intravenous administration toxicity study in the rat with a 4 week treatment-free period

PALO-99-08
T.Smith
Palonosetron hydrochloride: 9 months intravenous administration toxicity study

Carcinogenicity

AT 7455
P. Penumarthy
Oral gavage carcinogenicity study in rats with Palonosetron (RS-25259-197) – Study termination report
Comment: Final report abbreviated

AT 7464
P. Penumarthy
Oral gavage carcinogenicity study in mice with Palonosetron (RS-25259-197) – Study termination report
Comment: Final report abbreviated

Reproductive Toxicology

AT 6700
A.J. Sonderfan
Oral male fertility and reproduction study of RS-25259-007 in rats

AT 6267
F.D. Andrew
Intravenous male fertility study with RS-25259-197 in rats

AT 6750
A.J. Sonderfan
Oral female fertility and early embryonic development study of RS-25259-197 in rats

AT 6756
A.J. Sonderfan
Oral teratology study with RS-25259-197 in rats

AT 6755
A.J. Sonderfan
Oral teratology study with RS-25259-197 in rabbits

PALO-99-13
J. Ridings
Palonosetron hydrochloride: oral (gavage) study or pre- and postnatal development in the rat

Mutagenicity

AM 0400
R.H.C. San and S.J.Elson
Salmonella/Mammalian-microsome pre-incubation mutagenicity assay (Ames test) and Escherichia coli WP2 uvrA reverse mutation preincubation assay

AM 0402
C.A.H. Bigge and C.I. Sigler
CHO/HGPRT mutation assay

AM 0401
D.L. Putman and M.J. Morris
Chromosome aberrations in Chinese Hamster Ovary (CHO) cells

AM 0399
H. Murli
Mutagenicity test on RS-25259497 in vivo micronucleus assay

PALO-99-38
L. Golzio
Palonosetron: unscheduled DNA synthesis in rat liver cells in vivo

Juveniles Toxicology

PALO-99-25
J.E. Ridings
Palonosetron hydrochloride: range-finding toxicity study in juvenile rats by the subcutaneous mute

PALO-99-12
J.E. Ridings
Palonosetron hydrochloride: 28-day subcutaneous toxicity study in juvenile rats

PALO-99-41
J.E. Ridings
Palonesetron hydrochloride: range-finding toxicity study in juvenile dogs by the intravenous route

PALO-99-22
J.E. Ridings
Palonosetron hydrochloride: 28-day intravenous toxicity study in the juvenile dog

Special Toxicology Studies

AT 5923
A.J. Sonderfan
Vein irritation study in the rabbit with an intravenous formulation of RS-25259-197

PALO-99-30
W.D. Ruddock
Palonosetron: local intravenous tolerance study in the rabbit

AT 6276
F.D. Andrew et al.
Dermal irritation study in rabbits with transdermal formulations containing RS-25259-007

AT 6279
F.D. Andrew

Dermal sensitization study in guinea pigs with transdermal formulation containing RS-25259-007

CL 5911
A.J. Sonderfan
In vitro eompatibility testing of RS-25259-197 using human blood

PALO-99-28
B.V. Bailey and H. Renton
Validation of an analytical procedure for the determination of palonosetron and its metabolite RS-17825-007 in dog plasma (lithium heparin) using protein precipitation and liquid chromatography with tandem mass spectrometric detection

PALO-99-29
B.V. Bailey and K. Triffitt
Validation of an analytical procedure for the determination of palonosetron and its metabolite RS-17825-007 in mouse plasma (lithium heparin) using protein precipitation and liquid chromatography with tandem mass spectrometric detection

PALO-99-30
W.D. Ruddock
Palonosetron: local intravenous tolerance study in the rabbit

Toxicology summary

AT 6824
Non clinical toxicology summary of RS-25259

Comment: summary of studies AT 5921, AT 5939, AT 5922, AT 6284, AT 6268, AT 5962, AT 5963, AT 6329, AT 6328, AT 6665, AT 6751, AT 6787, AT 6700, AT 6267, AT 6750, AT 6756, AT 6755, AM 0400, AM 0402, AM 0401, AM 0399, AT 5923, AT 6276, AT 6279, CL 5911.

Clinical Know-how

The Clinical Know-how on the Compound is described in the following list and it includes all final reports available up to February 28, 2001.

Clinical Studies

Phase 1 Studies (Clinical Pharmacology)

Study 2092
(RS-25259-197
RGR/25259S2092/USA)

R. Stoltz
A single dose ascending dose safety and pharmacokinetics study of IV RS-25259 in healthy volunteers

Study 0100
(RS-25259-197
2525950100)
M. Tei
A single-dose safety and pharmacokinetics study of RS-25259 (IV bolus dose) in healthy volunteers

Study 0101
(RS-25259-197
2525950101)
M. Tei
A single-dose safety and pharmacokinetics study of RS-25259 (oral solution) in healthy volunteers

Study 2236
(RS-25259-007
RGR/25259S2236/USA)
R. Stoltz
Single ascending-dose safety and pharmacokinetics study of an oral solution of RS-25259-007 in healthy volunteers

Study 2216
(RS-25259-197
(RGR-259,2216/USA)
R. Stoltz
Plasma pharmacokinetics, metabolism, and excretion of [14C]-RS-25259-197 after intravenous injection

Study DM992
(RS-25259-197
Report number: DM992)
P. Weller
Dosimetry estimates for the intravenous administration of a single 56 uCi/70kg (10ug/kg) dose of [14C]-RS-25259-197 to human volunteers

Phase 2 Studies

Study 2330
(RS-25259-197
25259S2330)
S. Solish et al.
A dose-ranging efficacy, safety, and pharmacokinetic study of single intravenous doses of RS-25259 for prevention of nausea and vomiting in chemotherapy-naive cancer patients receiving highly emetogenic chemotherapy

Study 2332
(RS-25259-197
25259S2332)
S. Solish et al.
A dose-ranging efficacy, safety, and pharmacokinetic study of single oral doses of RS-25259 for prevention of nausea and vomiting in chemotherapy-naive cancer patients receiving highly emetogenic chemotherapy

Study 2500
(RS-25259-197
25259S2500)
D. McHugh et al.
A dose-ranging safety and efficacy comparison of four dose levels of intravenous RS-25259 to placebo in the prevention of postoperative nausea and vomiting following abdominal and vaginal hysterectomy

Study 2502
(RS-25259-197
25259S2502)
D. McHugh dal.
A dose-ranging safety and efficacy comparison of four dose levels of oral RS-25259 to placebo in the prevention of postoperative nausea and vomiting following laparoscopic procedures

Study 2120
(RS-25259-197
RGR/25259S2120/USA)
Rodriguez G.
A safety, antiemetic, and efficacy and pharmacokinetic study of single-dose IV RS-23259-197 in cisplatin-naive cancer patients receiving high-dose cisplatin chemotherapy

Regulatory Know-how

The Regulatory Know-how on the Compound is described in the following list and it includes all the correspondence with FDA from the submission of the IND 39,797, until February 28, 2001.

Note: Syntex correspondence from June 2nd 1992 to July 23rd 1998 is available only as hard copy and not as electronic file.

Date	*Document*	*Summary*
July 31,1998	Amendment #54	Transfer of Ownership from Syntex (USA.) inc. to Heisinn SA
August 3, 1998	Amendment #55	Transfer of Syntex IND 39,797 (RS-25259-197, Palonosetron) to Heisinn Heathcare SA
September 29, 1998	Telephone to Kati Johnson	IND 39,797 program input; end of phase 2 meeting information. IND 42,886 program status
November 5, 1998	Telephone to Dr. Jasti Choudary	Request for pre-meeting.
November 12, 1998	Amendment #56	Preclinical program backgronnd package. Study termination reports-Syntex carcinogenicity studies. Cross-reference to IND 42,886 Palonostron hydrochloride Oral
November 13, 1998	Telephone to Kati Johnson	Follow-up on pre-clinical submission (Amendment #56). Clinical meeting

		request End of phase 2 meeting guidance
December 1, 1998	Telephone to Kati Johnson	Follow-up on pre-clinical submission (Amendment #56). Clinical program discussion. End of phase 2 meeting planning
December 9, 1998	Telephone to Kati Johnson	Follow-up on pre-clinical submission (Amendment #56). End of Phase 2 meeting discussion
December 23, 1998	Amendment #57	Request for End of Phase 2 meeting
December 23/24, 1998	Telephone from Melody McNeil, and Doris	End of Phase 2 meeting request letter
December 28, 1998	Telephone to Melody McNeil	Requirement for hard copy submission of End of Phase 2 meeting request letter
December 30, 1998	Telephone to Melody McNeil	End of phase 2 meeting request letter sent to FDA by Federal Express
January 6, 1999	Telephone from Kati Johnson	End of phase 2 meeting scheduling

January 11, 1999	Telephone from Kati Johnson	EOP2 meeting scheduled for March 15, 1999
January 19, 1999	Fax from FDA	EOP2 meeting scheduled for March 15, 1999
January 25/26/27, 1999	Telephone to Kati Johnson	Oral route of administration in dog. Preclinical contents in background document. Feedback on Company questions for EOP2 meeting
January 27, 1999	Amendment #53	Preclinical program background package; information to Amendment #56
February 1, 1999	Letter from FDA	Request for further information to complete change of sponsorship (Amendments #54 and #55).
February 4, 1999	Telephone from Michelle Kidwell	EOP2 meeting date change to Match 10, 1999
February 5, 1999	Fax from FDA	EOP2 meeting scheduled for March 10
February 3, 1999	Telephone from Kati Johnson	Rationale for oral route in the dog toxicology study
February 15, 1999	Amendment #59	Background Document for March 10,

		1999 End of Phase 2 meeting
February 19, 1999	Telephone to Dorothy	Receipt of Background Document (assistant to Kati Johnson)
February 24, 1999	Telephone to Dorothy	EOP2 meeting location
February 24, 1999	Telephone to Kati Johnson	Feedback on background document
February 24, 1999	Telephone to Kati Johnson	Regulatory Agent (additional conversation to Feedback on Background document telephone contact).
March 2, 1999	Telephone from Melody McNeil	Studies 2500 and 2502 efficacy results
March 4, 1999	Telephone to Melody McNeil	EOP2 FDA pre-meeting discussion feedback
March 4, 1999	Fax to FDA	Desk copy of studies 2500 and 2502
March 8, 1999	Telephone to Dr. Goldkind	Reviewer comments
March 8/10, 1999	Telephone from/to Kati Johnson	Follow-up on meeting with Goldkind End of phase 2 meeting planning
March 29, 1999	Amendment #60	Reply to FDA letter of February 1, 1999

		about the change of Sponsorship
March 31, 1999	Telephone to Melody McNeil	EOP2- scheduling of Biopharm meeting Request for meeting minutes
April 6/8, 1999	Telephone to/from Melody McNeil	Scheduling of biophamnaceutics part of end of phase 2 meeting. Request for overheads
April 9, 1999	Letter from FDA	Minutes of the meeting with FDA on March 19, 1999 (EOP2)
April 27, 1999	Telephone to Melody McNeil	Feedback of End of phase 2 meeting. Request for special protocol assessment.
April 29, 1999	Letter from FDA	FDA comments and recommendations referred to amendments #56 and #58 and the EOP2
April 29, 1999	Amendment #61	Palonosetron Hydrochloride IV End of Phase 2 Meeting Biopharmaceutics Teleconference Meeting Document
May 7, 1999	Amendment #62	Palonosetron Hydrochloride IV Revised study termination

		report-Syntex carcinogenicity study in mice. Cross-reference to IND 44886 Palonosetron Hydrochloride Oral
May 21, 1999	Letter from FDA	EOP2 biopharmaceutics conference call meeting minutes
June 4, 1999	Telephone from Michelle Kidwell	EOP2 biopharmaceutics conference call meeting minutes
June 4, 1999	Fax from FDA	EOP2-Biopharrn teleconference meeting minutes
June 7, 1999	Amendment #63	Palonosetron Hydrochloride IV Overheads presented in End of Phase 2 meeting
August 19, 1999	Amendment #64	Palonosetron Hydrochloride IV Phase 3 and Commercial Formulation
September 24, 1999	Amendment #65	1999 Annual Report
October 15, 1999	Amendment #66	PALO 99-08, CIE 1063/1 "Palonosteron Hydrochloride: 26 Weck Intravenous Administration Toxicity Study in the

		Rat with a 4 Week intravenous-free Period" IND Safety Report: Initial Written report.
November 11, 1999	Amendment #67	Authorized representatives for IND 39,797
November 24, 1999	Amendment #68	Phase 3 efficacy protocol PALO 99-03. Request for Special Protocol Assessment and Agreement
November 24, 1999	Amendment #69	Phase 3 efficacy protocol PAW 99-04. Request for Special Protocol Assessment and Agreement
November 30, 1999	Amendment #70	Toxicology study PALO-99-08; CLE-1063/1 "Palo nosteron Hydrochloride: 26 Week intravenous Administration Toxicity Study in the Rat with a 4 Week intravenous-free Period" Information Amendment: Follow-up and Additional Information to IND Safety Report, IND Amendment #66

December 10, 1999	Amendment #71	Phase 3 efficacy protocol PALO 99-05. Request for Special Protocol Assessment and Agreement
December 22, 1999	Amendment #72 (Protocol Amendment)	New protocol, PALO 99-39 Phase I ADME study
January 10, 2000	Letter from FDA	Reply to questions on Protocol PALO-99-04 (amendment #69 dated November 24, 1999)
January 10, 2000	Letter from FDA	Reply to questions on Protocol PALO-99-03 (amendment #68 dated November 24, 1999)
January 27, 2000	Letter from FDA	Reply to questions on Protocol PALO-99-05 (amendment #71 dated December 10, 1999)
February 17, 2000	Amendment #73 (Information Amendment)	Notification of change of address and phone number for Dr. Craig Lehmann at August Consulting, Authorized Representative for the IND

April 7, 2000	Amendment #74 (Protocol Amendment)	New Protocols, Phase 3 Protocols PALO-99-03, PALO-99-04, PALO-99-05
April 11, 2000	Telephone from Melodi McNeil	FDA review time for proposed pediatric protocols for purposes of obtaining 6 months claimed exclusivity
April 24, 2000	Amendment #75	Proposed Pediatric Study Request (PPSR)
April 26, 2000	Amendment #76	Phase 3 efficacy protocol PALO 00-01. Request for Special Protocol Assessment and Agreement
May 22, 2000	Amendment #77 (Protocol Amendment)	New protocol, Phase 3 Protocol PALO-99-06.
June 5, 2000	Amendment #78	Request for teleconference with Pharm/Tox Reviewer to Discuss Segment 3 Reprotox Study
June 5, 2000	Telephone to Ms. Melodi McNeil	1. Receipt of ReproTox Teleconference 2. Phone And Fax numbers for IND Safety Reports

June 9, 2000	Letter from FDA	FDA response to the PALO-00-01 FDAMA special protocol review request
June 12, 2000	Telephone to Ms. Melodi McNeil	Dr. Choudary's pharm/ tox review of IND Amendement #78, request for teleconference to discuss segment 3 reprotox study
June 14, 2090	Letter from FDA	Reply to June 5 and 6, 2000 correspondence requesting a meeting to discuss the acceptability of a completed Segment 3 pre- and post-natal study of palonosetron in rats
June 19, 2000	Amendment #79 (Protocol Amendment)	New Investigators, Phase 3 protocols PALO-99-03, PALO-99-04, PALO-99-05, PALO-99-06
June 30, 2000	Amendment #80	IND Safety Report-In-Vitro Purkinje Fiber Dog Data
July 10, 2000	Telephone from Melodi McNeil	Dr Talarico's letter dated 9 June 2000, Item #5. Published

		Historical I'lacebo Control
July 11, 2000	Telephone from Melodi McNeil	(1) Expected FDA letter re PALO Segment 3 Reprotox Study (reply to IND #78, 5 June 2000) (2) FDA letter of 9 June 2000 clarification of number of historical placebo patients in the literature
July 11, 2000	Telephone from Melodi McNeil	(1) FDA reply letter to Reprotox teleconference request (2) Historical Placebo controls studies
July 19, 2000	Amendment #81 (Protocol Amendment)	New Investigators, Phase 3 Protocols PALO-99-03, PALO-99-04, PALO-99-05, PALO.99-06
August 4, 2000	Amendment #82	Follow up to IND Safety Report – In Vitro Purkinje Fiber Dog Data (IND Amendment #80, submitted June 30, 2000)
August 9, 2000	Letter from FDA	FDA reply to amend-ment dated June 30, 2000 (serial #80)

August 14, 2000	Amendment #83 (Protocol Amendment)	New protocol, Pediatric Protocol PALO-99-07
August 17, 2000	Telephone to Melodi McNeil	Dr. Talarico's letter (received today) dated August 9, 2000, regarding our original plans to exclude patients from phase 3 trials who are taking comeds which prolong QTc
August 18, 2000	Amendment #84 (Protocol Amendment)	New investigators, Phase 3 Protocols PALO-99-04, PALO-99-05, PALO-99-06
August 18, 2000	Letter from FDA	Incorrect Zip Code in the letter dated August 9, 2000
August 24, 2000	Amendment #85 (Information Amendment)	Chronic Toxicology Draft Reports for Palonosetron, 9-month in Dug, 26-week in at
August 24, 2000	Amendment #86 (Protocol Amendment)	New Protocols, Phase 1 protocols PALO-99-35 and PALO-99-51
August 24, 2000	Telephone to Melodi McNeil	Serial 482 Follow-up to Safety Report (Serial #80), plan to allow comeds which

		prolong QTc in Phase 3 Trials
August 29, 2000	Amendment #87 (Information Amendment)	Phase 1 protocols PALO-99-35 and PALO-99-51
September 8, 2000	Amendment #88 (Information Amendment)	ReproTox Final Reports for Palonosetron
September 8, 2000	Amendment #89 (Information on Amendment)	Chemistry, Manufacturing, and Controls • Revised Drug Substance Specifications • New Stability Indicating Methods for Drug Substance and Drug Product • 12-Month Stability for Phase 3 Clinical Batches
September 20, 2000	Amendment #90 (Protocol Amendments)	• New Investigators, Phase 3 Protocols PALO-99-03, PALO-99-04, PALO-99-05, and PALO-99-06. • Change in Protocols, Protocol Amendment No. 2 for PALO-99-03,

		PALO-99-04, PALO-99-05, and PALO-99-06.
September 22, 2000	Telephone to Melodi McNeil	FDA feedback regarding the pediatric protocol is expected in one week
September 26, 2000	Amendment #91 (Protocol Amendment)	New Investigators, Phase 3 Protocols PALO-99-03, PALO-99-05, PALO-99-06, and PALO-99-07
September 26,2000	Letter from FDA	FDA reply to Pediatric Study Request PALO-99-07
September 28, 2000	Amendment #92	2000 IND Annual Report
October 16, 2000	Amendment #93 (Information Amendment)	Rat Carcinogenicity Study PALO-98-03, Decreasing Number of Survivors in High Dose Female Group – Request for Goidance. Cross-reference to IND 42,886, Palonosetron Hydrochloride Oral
October 17. 2000	Telephone to Melodi McNeil	Dr. Choudary's preliminary feedback regarding the loss rate in the high dose female group in the Palonosetron Rat

		Carcinogenicity Study
November 3, 2000	Telephone to Ms. Alcock Patricia	NDA Field Copy to Responsible FDA District Office
November 6, 2000	Fax to Melodi McNeil (2)	Serial #93, October 16, 2000 – Request for confirmation of Dr. Chondary's feedback of October 17, 2000 regarding the loss rate in the high dose female group in the Palonosetron Rat Carcinogenicity Study
November 9, 2000	Telephone to Melodi McNeil	Request for confirmation from Dr. Choudary/FDA regarding his earlier feedback (FDA Communication Report, 17 October 2000) to address loss rates in the high dose female group of the Palonosetron rat carcinogenicity study
November 14, 2000	Letter from Dr. Talarico	FDA letter from Dr. Talarico (undated and unsigned) postmarked 9 Nov 2000 - FDA evaluation of

		juvenile rat and dog tox studies, follow-up FDA requests, and FDA request for full reports and data for dog and in-vivo CVS studies
November 17, 2000	Amendment #94 (Protocol Amendment)	New Investigators, Phase 3 Protocols PALO-99-03, PALO-99-04, PALO-99-05, and PALO-99-06
November 22, 2000	Amendment #95 (Request for teleconference)	Request for teleconference to discuss the proposed NDA CMC strategy
November 22, 2000	Telephone to Melodi McNeil	Request for tele-conference to discuss the proposed CMC NDA strategy
November 24, 2000	Telephone from Melodi McNeil	Proposed teleconfer-ence to discuss the Palonosetron CMC strategy
November 30, 2000	Amendment #96 (Request for teleconference)	Request for Teleconference to Discuss the Proposed Pediatric Protocol PALO-99-07
December 01, 2000	Telephone to Melodi McNeil	Arrangements for pediatric protocol teleconference (serial #96) and the CMC

		strategy teleconfcrence (serial #95)
December 07, 2000	Telephone to Heleo Wilson	Proposed dates/times for CMC strategy teleconference requested in Serial #95, submitted 22 Nov. 2000
December 12, 2000	Telephone to Robert DeLap	Status of ICH Common Technical Document (CM) Implementation at FDA for NDAs
December 12, 2000	Telephone to Helen Wilson	Arrangement of date/ time for requested Palonosetron CMC teleconference
December 12, 2000	Amendment #97 (Response to FDA request for information)	Reply to FDA Letter Postmarked November 9, 2000, Regarding the 28-Day Juvenile Rat and Dog Studies and the in vivo Dog Cardiovascular Safety Study
December 13, 2000	Telephone to Helen Wilson	CMC strategy FDA Teleconference – 31 Jan date no longer available per FDA. FDA suggests Jan 31th or Feb 2nd

December 14, 2000	Telephone to Helen Wilson	Arrangements for Palonosetron CMC Strategy Teleconference
December 15, 2000	Telephone to Helen Wilson	FDA proposed dates/ times to convene FDA pediatric PALO-99-07 protocol teleconference
December 15, 2000	Fax from FDA	FDA fax confirmation of date/time and planned FDA attendees for the CMC Strategy teleconference of Jan 30, 2001,9-10:30 AM, and FDA request for Word 97 diskette with list of Sponsor's attendees and specific questions
December 18, 2000	Telephone to Melodi McNeil	1) Date/time to convene the FDA pediatric PALO-99-07 protocol teleconference. 2) Subsequent planned teleconferences to discuss FDA's replies to Special Protocol Assessments (PALO-99-03, PALO-99.04,

		PALO-99-05, and PALO-00-01)
December 18, 2000	Amendment #98 (Protocol Amendment)	New Protocol, Phase 1 Protocol PALO-99-34
December 20, 2000	Amendment #99 (Protocol Amendment)	Now investigators, Phase 3 Protocols PALO-99-03, PALO-99-04- PALO-99-05, and PALO-99-06
December 21, 2000	Telephone to Melodi McNeil	Feasibility of face-to-face CMC strategy meeting at FDA instead of teleconference at same date/time as scheduled FDA teleconference
December 26, 2000	Fax from FDA	FDA fax confirming (1) Pediatric protocol teleconference February 8, 2001, and (2) CMC Strategy meeting January 30th instead of a teleconference
January 2, 2001	Amendment #100 (Protocol Amendment)	Change in Protocols, Protocol Amendment No. 3 to Phase 3 Clinical Protocols PALO-99-03, PALO-99-04, PALO-99-05, and PALO-99-06

January 16, 2001	Amendment #101 (Reply to FDA request for information)	List of Sponsor's attendees and specific questions for CMC Strategy meeting, 30 January 2001
January 17, 2001	Telephone to Melodi McNeil	Follow-up to assure FDA receipt of list of Sponsor's attendees and list of specific, questions/salient points in preparation for the FDA CMC Strategy meeting 30 January.
January 22, 2001	Amendment #102 (Reply to FDA request for information)	List of Sponsor's attendees and specific questions for the Pediatric Protocol PALO-99-07 Teleconference on 8 February 2001
January 23, 2001	Telephone to Helen Wilson	Diskette of FDA-Requested Sponsor's Attendees and Specific Questions for the Pediatric Protocol PALO-99-07 teleconference scheduled for Thursday S February 2001, 9:30-11 AM East Coast time

January 25, 2001	Amendment #103 (New Investigators)	Protocol Amendment, New Investigators, Phase 3 Protocols PALO-99-03, PALO-99-04, PALO-99-05 and PALO-99-06
January 31, 2001	Letter from Dr. Talarico	FDA letter from Dr. Talarico dated 31 Jan 2001 (in electronic signature page) regarding juvenile rat to data – FDA recommendation that – 07 patients be evaluated for ophthalmic function
February 7, 2001	Telephone to Melodi McNeil	Possible cancellation of FDA teleconference on 8 February 2001
February 8, 2001	Telephone to Melodi McNeil	FDA agreement with Helsinn's replies (submitted in IND Serial #96) to FDA's comments and request (FDA letter, 26 Sept 2000) regarding the PALO-99-07 pediatric protocol, and agreement to cancel the FDA/Helsinn Pediatric Protocol teleconference

		scheduled for 8 Feb 2001
February 21, 2001	Telephone to Melodi McNeil	Notification that the number of survivors in the high dose female group in the PALO-98-03 rat carcinoginicity study reached 20 on Feb 20, 2001, week 95 of the study, and request for FDA guidance
February 21, 2001	Amendment #104 (Pharmacology /Toxicology)	Rat Carcinogenicity Study PALO-98-03, Twenty Remaining Survivors in High Dose Female Group - Request for Guidance
February 22, 2001	Telephone from Melodi McNeil	Resuming treatment in the high dose female group, in the Palonosetron rat carcinogenicity study until 20% of the group (n-13) remains as survivors, then discontinue treatment, do not kill the animals, and allow the group to proceed to the end of the 104 week study

February 23. 2001	Telephone to Melodi McNeil	Resumption of treatment administration to high dose female rats in the PALO-98-03 rat carcinogenicity study
February 27, 2001	Amendment #105 (New Investigator)	Protocol Amendment, New Investigators, Phase 3 Protocols PALO-99-03, PALO-99-04, PALO-99-05, and PALO 99-06
February 27, 2001	Letter from FDA	FDA minutes of Palonosetron NDA CMC strategy meeting held January 30, 2001

SECOND APPENDIX

To an Agreement between HELSINN HEALTHCARE SA and MGI PHARMA INC. dated April 6th, 2001

PATENTS

US Patent "Tricyclic 5-HT, receptor antagonist?

Patent Number 5,202,333

Issued: April 13, 1993

Application Number: 7-704,565

Filed: May 22, 1991

Expected Expiry Date: May 22, 2011

THIRD APPENDIX

To an Agreement between HELSINN HEALTHCARE SA and MGI PHARMA dated April 6th, 2001

THE PRODUCTS.

Qualitative description of the Products as submitted to the United States Food and Drug Administration under TNT 39,797 Amendment # 64 and to the Therapeutic Products Programme in Canada under IND 9427-H0836-21C

1. Palonosetron HCI Intravenons injection is supplied as a sterile, isotonic solution in 5 ml Type 1 clear glass vials each containing 5 ml of product. The product is clear and colorless solution, and contains the equivalent of either 0.05 mg/mL or 0.15 mg/mL of Palonosetron free base. The formulation also contains mannitol as a tonicifying agent, edetate disodium as a chelating agent and citrate buffer to maintain the pH of the solution at the target pH of 5 (+/- 0.5).

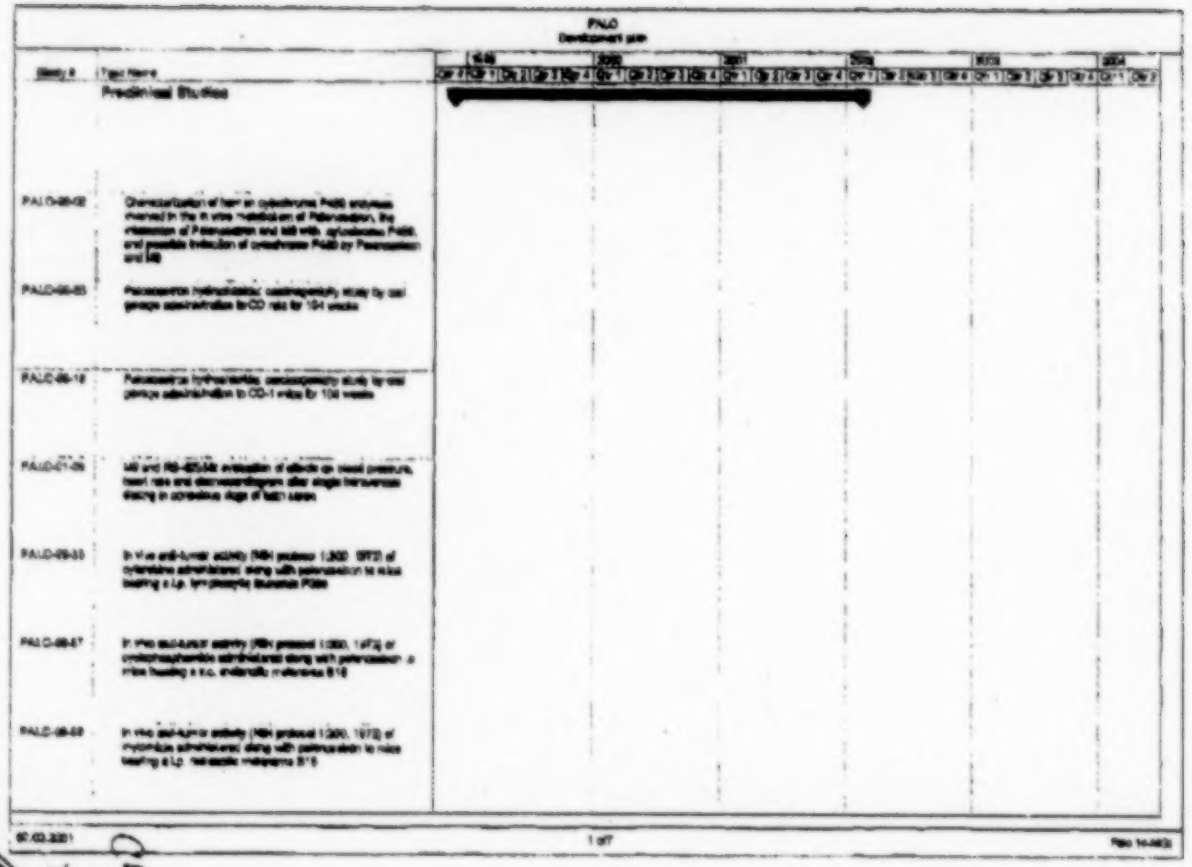
2. The product is terminally sterilized.

FOURTH APPENDIX

To an Agreement between HELSINN HEALTHCARE SA and MGI PHARMA dated April 6th, 2001

DEVELOPMENT CHART

See enclosed document, consisting of 7 pages.



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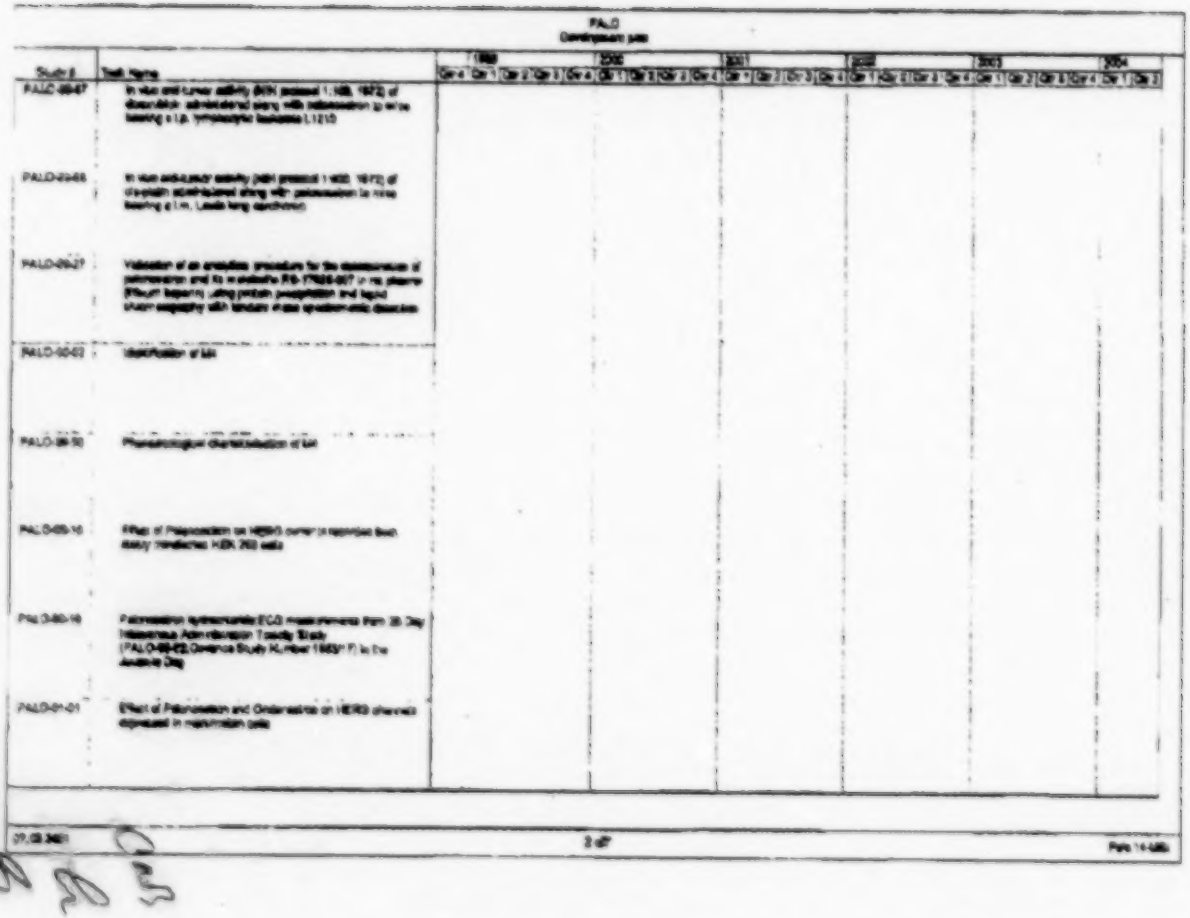

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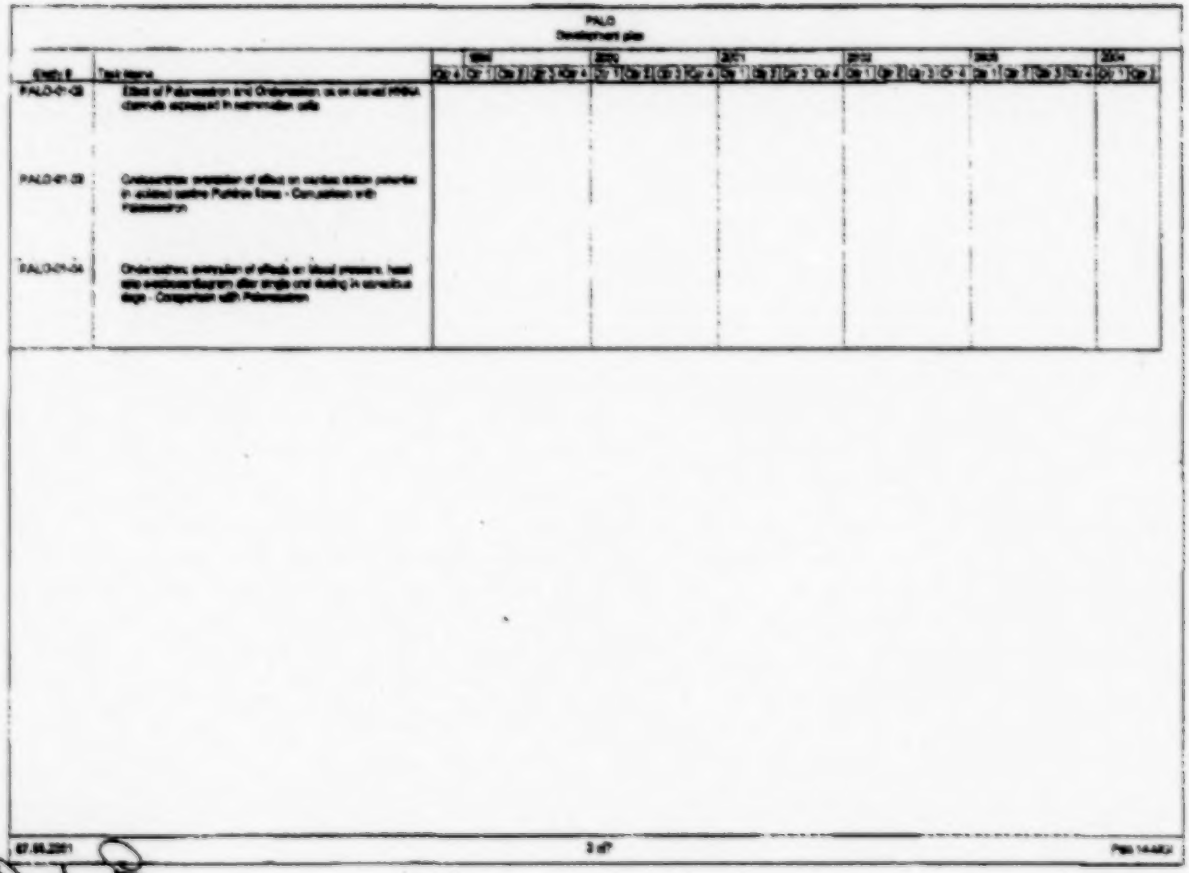

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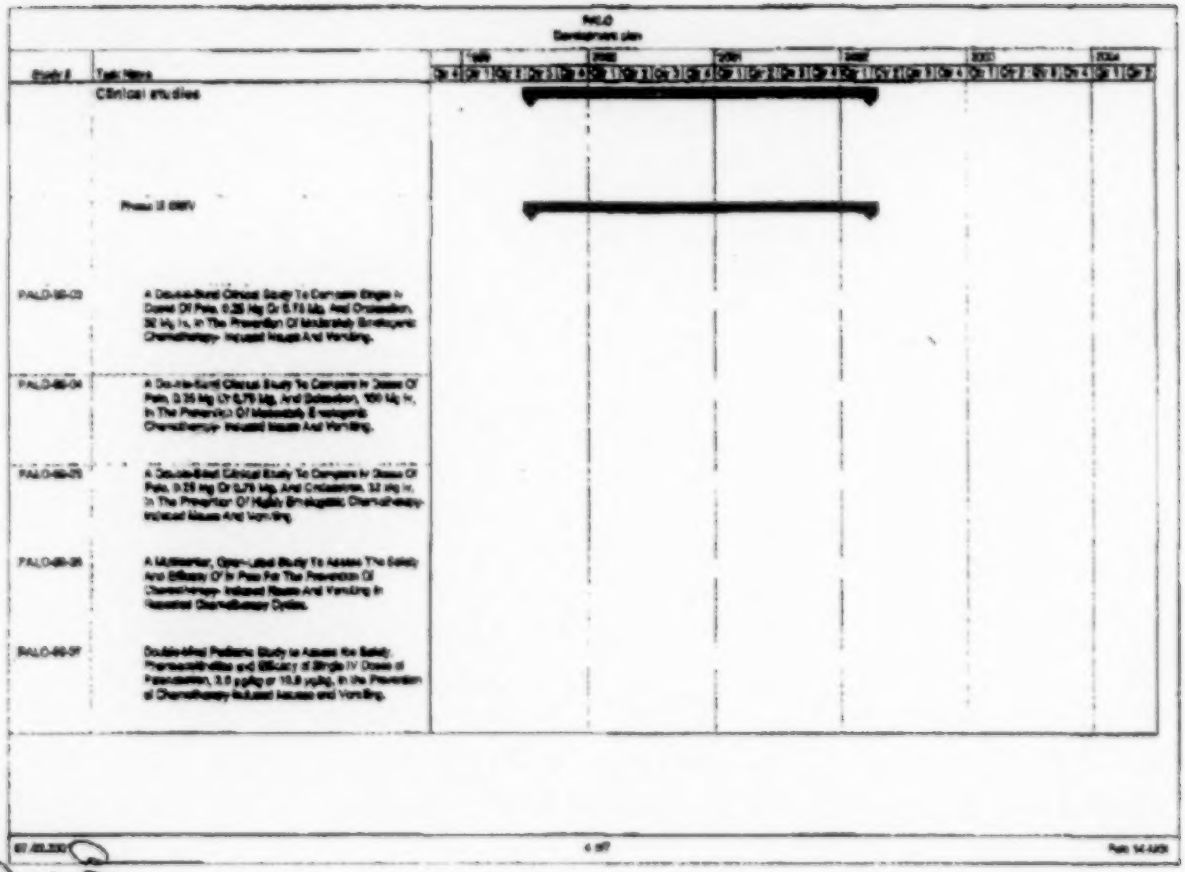

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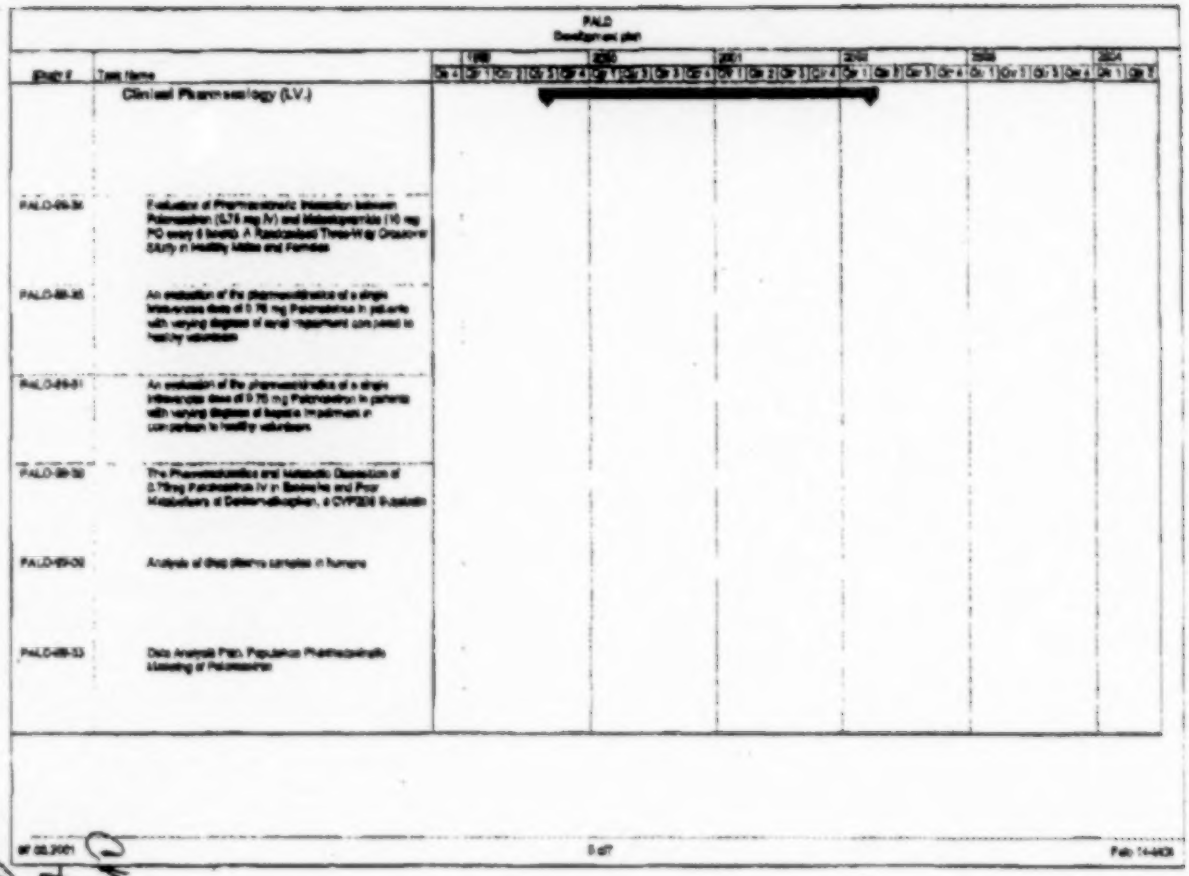

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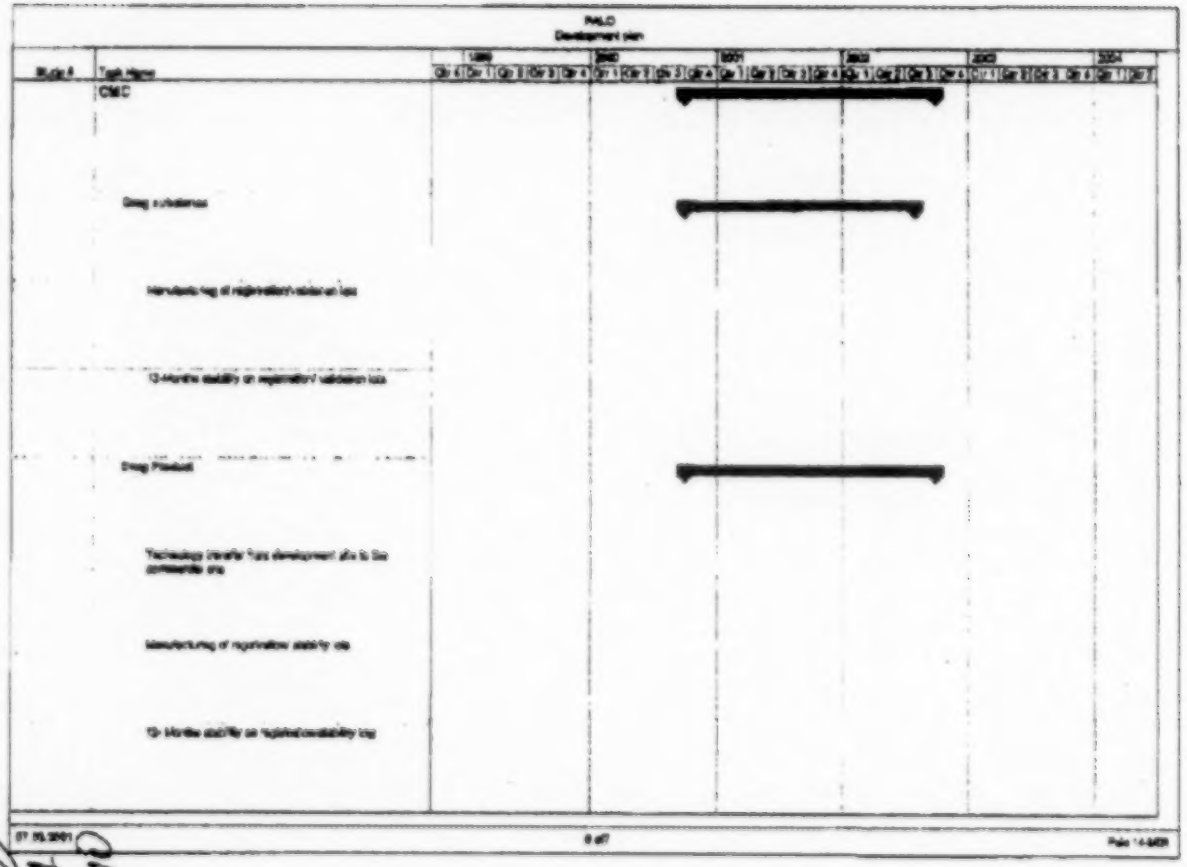
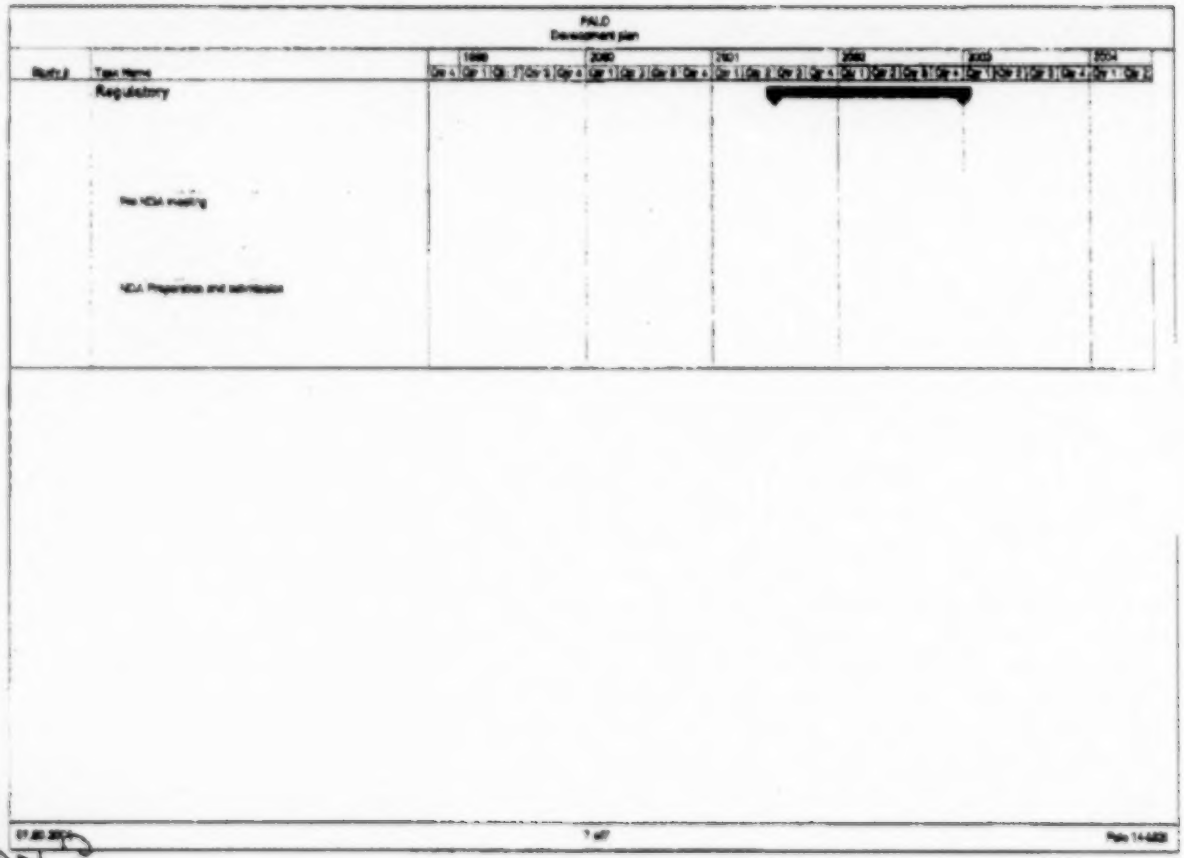


A01569

DTX-0115-0091

HIGHLY CONFIDENTIAL - OUTSIDE COUNSEL EYES ONLY



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FIFTH APPENDIX

To an Agreement between HELSINN HEALTHCARE SA and MGI PHARMA dated April 6th, 2001

HHC's POST-REGISTRATION REGULATORY ACTIVITIES

With reference to Article 4.5, the regulatory activities specifically listed hereunder shall be performed and carried out directly by HHC:

1. To pay the annual user fees for the maintenance of the drug product authorization in the Territory;

2. To update the authorization with new safety information that may affect the statement of contraindications, warnings, precautions, or adverse reactions in the approved labeling;

3. To comply with Good Manufacturing Practice regulations in 21 CFR Parts 210, 211;

4. To comply with applicable Labeling regulations in 21 CFR Part 20];

5. To comply with regulations for making changes in the product authorization in 21 CFR 3I4.7I;

6. To inform FDA of any communication relevant to the drug product received by authorities other thao in the Territory having impact in the Territory.

SIXTH APPENDIX

To an Agreement between HELSINN HEALTHCARE SA and MGI PHARMA INC. dated April 6th, 2001

ADVERSE EVENTS REPORTING

See enclosed document.

Provisions For The Exchange Of Safety Data With Commercial Partners

1. GENERAL

1.1 Each of HHC's Affiliated Company/Partner designates a qualified person who is the reference person for drug safety and will ensure that the local legal requirements for Adverse Events reporting are met in the territory of his/her responsibility. Any change in this position is to be notified by each of HHC's Affiliated Company/Partner within 15 calendar days to the Drug Safety Unit of HHC (hereinafter "HHC/DSU").

1.2 All adverse events should be available in one single point. The partner agrees that all safety data/cases involving the Product are stored in the Helsinn Healthcare Database as the reference global database. The partner has to process all local cases using its own database.

2. DATA PROCESSING AND EXCHANGE PROCEDURES

2.1 Adverse Event

For the purpose of this document, an adverse Event or Adverse Experience (AE) is defined as:

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a casual relationship with this treatment.

An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, For example), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

This definition includes intercurrent illnesses or injuries, exacerbation of pre-existing conditions, and adverse events occurring as a result of drug withdrawal, abuse, misuse or overdose. Adverse events observed during all periods of a clinical trial are to be recorded, including adverse events occurring during a period without trial medication. This also includes adverse events which are reported after a patient has completed the clinical study. Therapeutic failures during clinical trials are not considered to be adverse events.

Adverse Drug Reaction (ADR) / Adverse Reaction

Adverse drug reaction in this context is considered as synonymous with adverse reaction and suspected adverse drug reaction. Adverse drug reaction means a reaction which is harmful and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or treatment of disease or the modification of physiological function.

A reaction, contrary to an event, is characterised by the fact that a causal relationship between the drug and the occurrence is suspected, i.e. judged possible by the reporting or a reviewing health-care professional. If a reaction is spontaneously reported by a health-care professional, this usually implies a positive judgement from the reporter unless the reporter explicitly gives a negative judgement on the causal relationship.

Serious Adverse Reaction

This includes an adverse reaction which falls into one or more of the following categories:

fatal

life-threatening

results in persistent or significant disability/ incapacity

results in or prolongs hospitalisation.

This also includes congenital anomalies/birth defects and serious adverse clinical consequences associated with use outside the terms of the Summary of Product Characteristics (SPC) (including, for example, prescribed doses higher than those recommended), overdoses or abuse.

Medical judgement should be exercised in deciding whether a reaction is serious in other situations. Important adverse reactions that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the patient should be considered as actions.

2.1.1 Individual reporting of aft serious Adverse Events (AEs), irrespective of the source (e.g. spontaneous reports, Clinical Trials, literature, Regulatory Authorities), must be processed and transmitted by CIOMS form using the dedicated fax line by the Partner to HHC/DSU within 7 (seven) calendar days, after determination that the minimal criteria to handle the case have been met.

2.1.2 Reports (CIOMS form) as complete as possible for all non-serious AEs must be processed and forwarded to HHC/DSU on a monthly basis.

2.1.3 As regards. Clinical Trials, the "end of study safety report" should be sent to HHC/DSU.

2.1.4 The Partner is expected to follow up all serious AEs. Follow-up information (relevant medical information or any information affecting the case assessment) shall be transmitted where available in

the same manner as the initial information as described above (within seven calendar days).

2.1.5 All the US serious cases will be assessed and approved by HHC/DSU within 4 (four) calendar days.

2.1.6 All other serious cases (non-US) will be processed by HHC/DSU within 10 (ten) calendar days and CIOMS form will be transmitted to Partner. Tice eases have to be inserted in the local database-

2.1.7 The Partner is responsible for the submission to the authorities according to local time-frame of all relevant cases-

2.1.8 HHC/DSU is responsible for the preparation of the periodic safety update report (PSUR).

2.1.9 A PSUR will be prepared on a six monthly basis using the ICH format and will be distributed by HHC/DSU to all of HHC's Affiliated Companies and Licensces world-wide.

2.1.10 The Partner is responsible for the preparation and submission of periodic reports as required by local regulations. Any said report must be approved by HHC/DSU before notification, said approval to be considered as tacitly given in the absence of any communication by HHC within fifteen calendar days of receipt of the report.

3. LABELLING

3.1 HHC/DSU prepares a Company Core Data Sheet (CCDS) which covers material related to safety, indication, dosing, pharmacology and other information concerning the product.

3.2 It is therefore advisable that all HHC Affiliates/ Partners refer to the CCDS and maintain the Summary of Product Characteristics (SPC) and leaflets as

close as possible to the "reference document" (CCDS) in the different countries and for the different companies marketing the products under HHC's license all over the world. Changes specifically requested by local Regulatory Authorities, if any, are inserted in the SPCs and leaflets and HHC/DSU has to be informed of the changes. A copy of the revised SPC/leaflet will be sent to HHC/DSU.

4. OTHER SAFETY DATA

4.1 The partners have to agree mutually exchange of information regarding any safety aspects of the Products. This includes information on any restrictions given by the Health Authority to the Product and warning and contraindications on product information texts (SPC, leaflets).

5. REPORTING TO THE REGULATORY AUTHORITIES

5.1 Each Partner is responsible locally for safety monitoring, management and reporting of individual case reports in an expedited manner, when applicable, and for the submission of the HHC Periodic Safety Update Reports (PSUR) to the relevant Regulatory Authorities in accordance with the current regulation of each country.

5.2 If it is deemed necessary the PSUR provided by HHC/DSU on a six monthly basis will be completed/ integrated with additional data by the Partner to comply with local requirements and after agreement with HHC/DSU.

5.3 Copy of any written communication and document submitted to the Regulatory Authorities, where different from the PSUR provided by HHC, must be forwarded to HHC, possibly before submitting

it to the Regulatory Authority for HHC's approval, which shall be considered as tacitly given in the absence of any communication by HHC within fifteen calendar days of receipt of the draft.

Reference address for any safely information transmission is the following;

Drug Safety Unit

MEDICAL AFFAIRS DIVISION HELSINN
HEALTHCARE SA
P.O. Box 357
6915 Pambio-Noranco
phone +41/91 985 21 21
Fax +41/91 985 21 71

SEVENTH APPENDIX

To an Agreement between HELSINN HEALTHCARE SA and MCA PHARMA INC dated April 6th, 2001

PRODUCTS RECALL PROCEDURE

See enclosed documents.

Definition Of Responsibilities For Handling Of Product Complaints, NDA-Field Alerts, Market Withdrawals, Product Recall

1. COMMUNICATION/RESPONSIBILITY/ AUTHORITY

Each Party shall promptly inform the other Party of any event, including but not limited to Product Complaint or NDA-Field Alerts, that might require the necessity of initiating a Product Recall or Market Withdrawal.

HHC and MGI shall co-operate in good faith to decide whether or not such actions need to be implemented. In case of disagreement, the final decision will be to proceed as long as one of the two parties decides to effect the Product recall or the Market Withdrawal.

2. COORDINATION OF PRODUCT RECALL OR MARKET WITHDRAWAL ACTIVITIES

In any event, with respect to any Recall, Product Withdrawal, or Field Correction. MGI shall make all contacts with the FDA in accordance with the terms and conditions of this Agreement and shall be responsible for coordinating all the necessary activities in connection with such Recall, Product Withdrawal or Field Correction.

3. RECALL TERMINATION

MGI shall provide HHC with a document that demonstrates that it is reasonable to assume that the Product subject of the recall or market withdrawal has been removed and proper disposition or corrections have been made.

4. LIABILITY FOR RECALL. COSTS

If a Recall, Product Withdrawal or Field Correction is necessary for any reason, HHC and MGI shall each bear the costs of the recall in proportion to each Party's responsibility for the error necessitating the recall, including but not limited to costs associated with defending or settling claims for product liability, receiving and administering the recalled Product and notification of the recall to those persons whom MGI deems appropriate.

5. PROCEDURES

Procedures regulating the activities to be performed for managing Product Complaints, NDA-Technical Field Alert Report, Product Recall and Market Withdrawals shall be mutually developed, agreed and approved between MGI and HHC.

6. CONFIDENTIALITY

Without prejudice to reporting obligations towards Regulatory Authorities provided for in this Appendix and/or established by applicable laws and regulations, all communications relating to any recall, product withdrawal or field correction shall be kept confidential in accordance with the provisions of Article 14 of this Agreement

EIGHT APPENDIX

To an Agreement between HELSINN HEALTHCARE SA and MGI PHARMA INC- dated April 6th, 2001

ESCROW AGREEMENT

See enclosed document

ESCROW AGREEMENT

Pursuant to this Escrow Agreement, dated _____ (the "Agreement"), HELSINN HEALTHCARE SA and MGI PHARMA, INC. (the "Parties") hereby establish Escrow Account No. _____ (the "Account") with U.S. Bank Trust National Association, a national banking association (the "Agent"), to be maintained and administered for the purposes described in Schedule I attached hereto in accordance with the following terms and conditions:

The Parties are party to a Licence Agreement of even date herewith pursuant to which MGI PHARMA, INC. is obligated to make certain milestone payments to Helsinn Healthcare SA.

The funds and/or property described on Schedule I attached hereto and incorporated herein (the "Asset?) shall be deposited in the Account upon delivery thereof to the Agent at its office in St. Paul, Minnesota by the depositors identified below (the -Depositors") no later than 15 days from the date of this Agreement. The Agent is hereby authorized and directed by each of the Parties, as their escrow agent, to hold, deal with and dispose of the Assets as provided in the Instructions set forth in Schedule H attached hereto and incorporated herein; subject, however, to the terms and conditions set forth below, which in all events, shall govern and control over any contrary or inconsistent provisions contained in Schedules I or II attached hereto.

1. Agent's Duties. The Agent shall hold, deal with and dispose of the Assets deposited to the Account in accordance with the provisions set forth in this Agreement and the Schedules attached hereto. The

Agent's duties and responsibilities shall be limited to those expressly set forth in this Agreement, and the Agent shall not be subject to, or obliged to recognize, any other agreement between any or all of the Depositors or any other persons even though reference thereto may be made herein; provided, however, that this Agreement may be amended at any time or times by an instrument in writing signed by the Parties hereto and the Agent. The Agent shall not be subject to or obligated to recognize any notice, direction or instruction of any or all of the Depositors or of any other person, except as expressly provided for and authorized in Schedule 11.

2. Court Orders or Process. If any controversy arises between the Parties to this Agreement, or with any other party, concerning the subject matter of this Agreement, its terms or conditions, the Agent will not be required to determine the controversy or to take any action regarding it. The Agent may hold all documents and funds and may wait for settlement of any such controversy by final appropriate legal proceedings or other means. In such event, the Account shall collect interest in accordance with Section 4 and 6 hereof. The Agent is authorized, in its sole discretion, to comply with orders issued or process entered by any court with respect to the Account, the Assets or this Agreement, without determination by the Agent of such court's jurisdiction in matter. if any Assets are at any time attached, garnished, or levied upon under any court order, or in ease the payment, assignment, transfer, conveyance or delivery of any such property shall be stayed or enjoined by any court order, or in case any order, judgment or decree shall be made or entered by any court affecting such property or any part thereof, then in any such events the Agent is authorized, in its sole discretion, to rely

upon and comply with any such order, writ, judgement or decree which it is advised by legal counsel of its own choosing is binding upon it; and if the Agent complies with any such order, writ, judgment or decree, it shall not be liable to any of the Depositors or to any other person, firm or corporation by reason of such compliance even though such order, writ, judgment or decree may be subsequently reversed, modified, annulled, set aside or vacated.

3. Agent's Actions and Reliance. The Agent shall not be personally liable for any act taken or omitted by it hereunder if taken or omitted by it in good faith and in the exercise of its own best judgment, The Agent shall also be fully protected in relying upon any written notice, instruction, direction, certificate or document signed by each of the Parties which in good faith it believes to be genuine.

4. Collections. Unless otherwise specifically indicated in Schedule 11, the Agent shall proceed as soon as practicable to collect any cheeks, interest due, matured principal or other collection items with respect to Assets at any time deposited in the Account. All such collections shall be subject to the usual collection procedures regarding items received by the Agent for deposit or collection- The Agent shall not be responsible for any collections with respect to Account Assets if the Agent is not registered as record owner thereof or otherwise is not entitled to request or receive payment thereof as a matter of legal or contractual right. All collection payments shall be deposited to the Account, except as otherwise provided in Schedule 11. Agent shall not be required or have a duty to notify anyone of any payment or maturity under the terms of any instrument, security or obligation deposited in the Account, nor to take any

legal action to enforce payment of any check, instrument or other security deposited in the Account. The Account is a safekeeping escrow account, and no interest shall be paid by Agent on any money deposited or held therein, except as provided in Section 6 hereof

5. Agent Responsibility. The Agent shall not be liable to any Party for consequential damages (including, without limitation lost profits), losses or expenses in performing its duties under this Agreement, except for gross negligence or willful misconduct on the part of the Agent. The Agent shall not be responsible or liable for the sufficiency or accuracy of the form, execution, validity or genuineness of documents, instruments or securities now or hereafter deposited in the Account, or of any endorsement thereon, or for any lack of endorsement thereon, or for any description therein. Registered ownership of or other legal title to Assets deposited in the Account shall be maintained in the name of the Agent. The Agent may maintain qualifying Assets in a Federal Reserve Bank or in any registered clearing agency (including, without limitation, the Depository Trust Company) as the Agent may select, and may register such deposited Assets in the name of the Agent or its agent or nominee on the records of such Federal Reserve Bank or such registered clearing agency or a nominee of either. The Agent shall not be responsible or liable in any respect on account of the identity, authority or rights of the persons executing or delivering or purporting to execute or deliver any such document, security or endorsement or this Agreement.

6. Investments. All monies held in the Account shall be invested by the Agent in its name or its nominee's name, in such instruments or securities as expressly authorized in Schedule III. The Agent may

sell securities (including shares or units in any money market mutual funds) to make any payments from the Account as provided hereunder. The Agent shalt not be responsible for the selection, quality or maturity of such investments, or for the timely reinvestment of interest or maturity proceeds thereof except as provided in the immediately following paragraph.

Monies credited to any account or fund maintained hereunder which are uninvested pending disbursement or receipt of proper investment directions or as directed herein, may be deposited to and held in a non-interest bearing demand deposit account established with the Commercial Banking Department of the Agent or with any bank affiliated with the Agent, without the pledge of securities to or other collateralization of such deposit accounts.

The Parties acknowledge and agree that the Agent is authorized to invest from or through its trust department or U.S. Bank National Association or any other bank affiliated with the Agent through common cannel by U.S. Bancorp.

7. Notices/Directions to the Agent. Notices and directions to the Agent from Depositors, or from other persons authorized to give such notices or directions as expressly set forth in Schedule Il, shall he in writing and signed by an authorized representative as identified pursuant to Schedule Il, and shall not be deemed to be given until actually received by Agent's employee or officer who administers the Account. The

Agent shall not be responsible or liable for the authenticity or accuracy of notices or directions properly given hereunder if the written form and execution thereof on its face purports to satisfy the requirements applicable thereto as set forth in

Schedule 11, as determined by Agent in good faith without additional confirmation or investigation.

8. Books and Records. The Agent shall maintain books and records regarding its administration of the Account, and the deposit, investment, collections and disbursement or transfer of Assets, shall retain copies of all written notices and directions sent or received by ii in the performance of its duties hereunder, and shall afford each Depositor and each Party reasonable access, during regular business hours, to review and make photocopies (at Depositor's cost) of the same.

9. Disputes Among Depositors and/or Third Parties. In the event the Agent is notified of any dispute, disagreement or legal action between or among any of the Depositors, and/or any third parties, relating to or arising in connection with the Account, the Assets or the performance of the Agent's duties under this Agreement, the Agent shall be authorized and entitled, subject to Section 2 hereof, to suspend further performance hereunder, to retain and hold the Assets then in the Account and take no further action with respect thereto until the matter has been fully resolved, as evidenced by written notification signed by the Parties and any other parties to such dispute, disagreement or legal action.

10. Notice by Agent. Any notices which the Agent is required or desires to give hereunder to any of the Parties shall be in writing and may be given by mailing the same to the address of the Party indicated below (or to such other address as said Party may have theretofore substituted therefor by written notification to Agent), by United States certified or registered mail, postage prepaid. Whenever under the terms

hereof the time for Agent's giving a notice or performing an act falls upon a Satarday, Sunday, or holiday, such time shall be extended to the next business day.

If to MGI PHARMA, INC.:

MGI PHARMA, Inc.
6300 West Old Shakopee Road
Suite 110
Bloomington, MN 55438
USA
Attention: Manager, Legal Affairs
Facsimile: (952) 346-4800

If to Helsinn Healthcare SA

Helsinn Healthcare SA
P.O. Box 357
6915 Pambio-Noranco
Switzerland
Attention: Legal Department
Facsimile: 01141919932122

11. Legal Counsel if the Agent believes it to be reasonably necessary to consult with counsel concerning any of its duties in connection with the account or this Agreement, or in case the Agent becomes involved in litigation on account of being the Agent hereunder or on account of having received property subject hereto, then in either case, its costs, expenses, and reasonable attorney's fees shall he paid by the Parties in equal amounts.

12. Agent Compensation. The Agent shall he paid by MGI PHARMA, INC. a fee for its services as set forth on Schedule IV attached hereto and incorporated herein, and reimbursed by MGI PHARMA, INC. for its reasonable costs and expenses incurred, an invoice of which such costs and expenses shall be provided to the

Parties. If the Agent's fees, or reasonable costs or expenses, provided for herein, are not promptly paid fifteen days following receipt of written notice of an overdue payment, the Agent shall have the right to sell such portion of the Assets held in the Account as necessary and reimburse itself therefor from the proceeds of such sale or from the cash held in the Account. In the event that the conditions of this Agreement are nut promptly fulfilled, or if the Agent, at the written request of the Parties, renders any service not provided for in this Agreement, or if the Parties request, in writing, a substantial modification of its terms, or if the Agent is made a party to, or intervenes in, any litigation pertaining to this Agreement, the Agent shall, upon the written approval of the parties for such costs, be reasonably compensated for such extraordinary services and reimbursed for all reasonable costs, reasonable attorney's fees, and expenses occasioned by such default, delay, or litigation and the Agent shall have the right to retain only the equivalent amount of such unpaid costs and expenses from the Assets at such time held by the Agent io the Account until such compensation, fees, casts, and expenses are paid. These sums shall be paid upon demand by the Parties in equal amounts. The Depositors and their respective successors and assigns agree jointly and severally to indemnify and hold the Agent harmless against any and all losses, claims, damages, liabilities, and expenses, including reasonable costs of investigation, reasonable counsel fees, and disbursements that may be imposed on the Agent or incurred by the Agent in connection with the performance of his/her duties under this Agreement, including but not limited to any litigation arising from this Agreement or involving its subject matter, except for losses, claims, damages, liabilities, and expenses

arising from the gross negligence or willful misconduct on the part of the Agent. The Agent shall have a first lien on the property and papers held under this Agreement for such compensation and expenses.

13. Agent Resignation. It is understood that the Agent reserves the right to resign at any time by giving written notice of its resignation, specifying the effective date thereof, to the Depositors, which such effective date shall be at least 30 days from the date of the written notice. Within 30 days after receiving the aforesaid notice, the Depositors agree to appoint a successor escrow agent reasonably satisfactory to each of the Parties to which the Agent may transfer the Assets then held in the Account, less its unpaid fees, costs and expenses. The Agent shall promptly transfer the Assets then held in the Account upon receipt of the notice of appointment of the successor escrow agent. If a successor escrow agent has not been appointed and has not accepted such appointment by the end of the 30-day period, the Agent may apply to a court of competent jurisdiction for the appointment of a successor escrow agent, and the costs, expenses and reasonable attorney's fees which the Agent incurs in connection with such a proceeding shall be paid by MGI PHARMA, INC.

14. Escrow Termination. If, as provided in Schedule II, this Agreement shall not have previously terminated and a dispute, disagreement or legal action pursuant to Section 9 hereof has not commenced, then it shall automatically terminate on the second anniversary of the date of this Agreement, at which time the Assets, plus any interest earned thereon, then held in the Account, less the Agent's unpaid fees, costs and expenses shall be distributed in the following manner:

Returned to MGI PHARMA, INC. by wire transfer to:

US Bank Minnesota

601 Second Avenue South

Minneapolis, MN USA 55402

ABA# 0910-0002-2

FBO MGI PHARMA,

A/C# 1-702-2513-9162

15. Governing Law. This Agreement shalt be construed, enforced, and administered in accordance with the laws of the State of Minnesota.

16. Automatic Succession Any company into which the Agent may be merged or with which it may be consolidated, or any company to whom Agent may transfer a substantial amount of its Escrow business, shall be the Successor to the Agent without the execution or filing of any paper or any further act on the part of any of the Parties, anything herein to the contrary notwithstanding.

IN WITNESS WHEREOF, the parties have duly executed this Agreement as of the day and year first above written.

Name and Address	Signature and Title
Dr. Riccardo Braglia or	_____
	Managing Director
Dr. Enrico Braglia	_____
	Managing Director

HELSINN HEALTHCARE SA
P.O. Box 357
6915 Pambio-Horanco
SWITZERLAND

DEPOSITORS

Charles N. Blitzer or _____
Chief Executive Officer

Leon O. Moulder, Jr _____
Executive Vice President

MGI PHARMA, INC.
6300 West Old Shakopee Road
Suite 110
Bloomington, MN 55438-2318
USA

U.S. Bank Trust National Association, as Agent

By:_____

SCHEDULE
PURPOSE OF ESCROW

The purpose of this escrow arrangement is to provide for appropriate, timely payment of two milestone payments under the License Agreement between HELSINN HEALTHCARE SA and MGI PHARMA, INC. dated _____, 2001.

No later than 15 days from the date of execution of this Agreement, MGI PHARMA, INC. shall deposit $6,000,000 into the Account.

SCHEDULE II
INSTRUCTIONS OF DEPOSITORS

All escrow monies are to be invested as indicated on Schedule HI until disbursement is needed as follows:

$2 million is to be wired for the benefit of HELSINN HEALTHCARE SA six months after execution of this Agreement

$4 million is to be wired for the benefit of HELSINN HEALTHCARE SA upon confirmation that a Type B pre-NDA meeting related to palonosetron has occurred with the United States Food and Drug Administration. This confirmation may take the form of a copy of FDA's record of meeting attendees or a copy of FDA provided minutes from the meeting to be provided by representatives of either HELSINN HEALTHCARE or MGI PHARMA. Alternatively, written acknowledgment of the meeting's occurrence from one of the MGI PHARMA signatories to this escrow agreement may serve. The Parties shall give the Agent a joint written notice to such effect.

Wire transfers to HELSINN HEALTHCARE should be made using the following instructions:

UBS SA
Via Pretorio 9
CH-6901 Lugano
Swift UBSW CH ZH69A
A/C# 459.089.62L HELSINN

MGI PHARMA is entitled to all of the investment earnings of the escrowed assets, and any assets remaining after the disbursements listed above have been made will be paid for the benefit of MGI PHARMA, INC. to:

US Bank Minnesota
60I Second Avenue South
Minneapolis, MN USA 55402
ABA# 0910-0002.2 FBO
MGI PHARMA, INC.
A/C# 1-702-2513-9162

SCHEDULE III

In the absence of specific written direction to the contrary, you are hereby directed to invest and reinvest proceeds and other available monies in any of the following funds/deposits as permitted by the operative documents (SEE BELOW DESCRIPTION OF INVESTMENT VEHICLES AND FEE BASIS FOR EACH). Please mark one space with an X for the investment vehicle selection.

___ First American Treasury Obligations Fund (Class D)*

___ First American Government Obligations Fund (Class D)*

_X_ First American Prime Obligations Fund (Class D)*

___ First American Tax Free Obligation Fund (Class D)*

___ U.S. Bank Money Market Deposit Account**

*First American Funds:

SEE FIRST AMERICAN FUNDS, INC. PROSPECTUS WHICH HAS BEEN/OR WILL BE PROVIDED. NOTE THAT THE ABOVE FUNDS' INVESTMENT ADVISOR AND CUSTODIAN ARE SUBSIDIARIES OF U.S. BANCORP. SHARES OF THE FUNDS ARE NOT DEPOSITS OR OBLIGATIONS OF, OR GUARANTEED BY, ANY BANK INCLUDING U.S. BANK NATIONAL ASSOCIATION, U.S BANK TRUST NATIONAL ASSOCIATION, OR ANY OF THEIR AFFILIATES, NOR ARE THEY INSURED BY THE FEDERAL DEPOSIT INSURANCE CORPORATION, THE FEDERAL RESERVE BOARD OR ANY OTHER AGENCY. AN INVESTMENT IN THE FUNDS INVOLVES INVESTMENT RISK,

INCLUDING POSSIBLE LOSS OF PRINCIPAL. Neither U.S. Bank Trust nor U.S. Bank will vote proxies for the First American Funds. Proxies will be mailed to your designated voter.

Fee Basis; Approval of investment in any of these First American mutual funds includes approval of the fund's fees and expenses as detailed in the prospectus, including advisory and custodial fees and 12b-1 shareholder service expenses, which fees and expenses are paid to U.S. Flank Mist or U.S. Bank, subsidiaries of U.S. Bancorp.

**U.S. Bank Money Market Deposit Account

This fund is a bank time deposit of U.S. Bank National Association. The interest rate paid is the average of the Goldman ILA Prime Fund, the Shearson Temp and Federated Prime Funds. Selection includes authorization to invest in deposits of U.S. Bank National Association or any other bank affiliated with U.S. Bank Trust National Association through common control by U.S. Bancorp.

Fee Basis: In selecting the U.S. Bank Money Market Deposit Account, authorization is given to deduct an administrative management fee of 40 basis points (.0040) (subject to change upon notice) against the average daily fund balances, netted from investment earnings or monies.

If U.S. Bank Trust National Association is directed, to invest available account monies pursuant to the operative documents, in a mutual fund not managed or sponsored by an affiliate of U.S. Bank Trust National Association, it may charge such fund, or the fund's investment manager, a fee for services for fund share accounting and administrative services, not to exceed 40 basis points (.0040) of 1 percent of the

account monies so invested in the fund. Payment of such service fees will not result in any increase in fees charged against the fund's assets or earnings above the fee and expense levels otherwise established and charged for the fund, as disclosed in the fund prospectuses.

SCHEDULE IV

Agent's Fees

All fees shall be paid by MGI PHARMA, INC. as follows:

Acceptance Fee: $ 1,250.00

(Includes review of Agreement and establishing procedures and controls)

First year's administrative fee:
(payable in arrears)

If all funds are invested in a Money Market Fund utilized by U.S. Bank Trust $ 1,500.00

If funds are invested other than above $ 2,000.00

Subsequent year administration fee: as above
(payable in arrears)

Charges

Disbursements (checks or wires) $20.00 Each

Fee for security transactions:

A. Settlement of trades in the open market at direction of customer $75.00 per buy or sale
$50.00 per maturity

B. Trading in authorized Money Market Funds utilized by U.S. Bank Trust as Prospectus or Schedule indicates

Out-of-Pocket Expenses: Billed at Cost

Expenses including but not limited to stationery, postage, telephone, insurance, shipping, Telex/ Telegram, services of outside counsel and agents. (Plus indirect out-of-pocket at 3% of administrative fee.)

Note: Charges for performing other escrow services not specifically covered in this schedule will be determined by an appraisal of the services rendered. The fees shown in this schedule may be increased annually.

NINTH APPENDIX

To an Agreement between HELSINN HEALTHCARE SA and MGI PHARMA INC. dated April 6th, 2001

MGI'S UNIT SALES BASE FORECASTS ANNUAL MINIMUM SALES

See enclosed document.

Ninth Appendix

Value $ (000's) and Units (000's)

1) USA HGE UNIT SALES FORECAST

	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5	YEAR 6	YEAR 7	YEAR 8	YEAR 9	YEAR 10
Units	118	298	662	875	785	666	549	434	391	212

2) USA ANNUAL MINIMUM SALES

Minimum annual sales	$ 11'123	$ 28'826	$ 65'915	$ 89'748	$ 82'906	$ 72'432	$ 60'902	$ 51'873	$ 46'014	$ 25'668

HIGHLY CONFIDENTIAL - OUTSIDE COUNSEL EYES ONLY

A01595

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TENTH APPENDIX

To an Agreement between HELSINN HEALTHCARE SA and MGI PHARMA INC. dated April 6th, 2001

PROMOTION AND MARKETING ACTIVITIES

See enclosed document.

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Tenth Appendix

$(000's)

USA MARKETING ACTIVITIES

	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5	5Y TOTAL	YEAR 6	YEAR 7	YEAR 8	YEAR 9	YEAR 10
Sales force expenses	$ 8750	$ 8750	$ 8750	$ 8750	$ 4375	$ 39375	$ 4375	$ 4375	$ 4375	$ 4375	$ 4375
Marketing expenses	$ 11700	$ 9000	$ 9000	$ 8000	$ 7000	$ 44000	$ 7000	$ 3000	$ 3000	$ 3000	$ 3000
Medical expenses	$ 400	$ 300	$ 250	$ 250	$ 250	$ 1450	$ 250	$ 250	$ 250	$ 250	$ 250
Total selling expenses	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Maximum sales force 40 full time sales representatives

Appropriate number of visits to key doctors as per the average of the market for each class of products

Participation to the major congresses in oncology (e.g. ASCO)

HIGHLY CONFIDENTIAL - OUTSIDE COUNSEL EYES ONLY

HELSN0138228

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EXHIBIT O

Supply and Purchase Agreement

between

HELSINN BIREX PHARMACEUTICALS LTD

and

MGI PHARMA, INC.

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THIS AGREEMENT (hereinafter called "Agreement") is effective as of this 6th day of April 2001 (hereinafter called "Effective Date"), between HELSINN BIREX PHARMACEUTICALS LTD, a corporation organized and existing under the law of the Republic of Ireland and having its registered office at Damastown, Mullhuddart, Dublin 15, Republic of Ireland (hereinafter called "HBP") of the one part, and MGI PHARMA, INC., a corporation organized and existing under the law of the state of Minnesota, United States of America and having its registered office at 6300 West Old Shakopee Road, Suite 110, Bloomington, MN 55438-2318, USA thereinafter called "MGI"), of the other part.

RECITALS

a. MGI carries on business as a pharmaceutical company and. in particular for the purpose of this Agreement, has entered into a License Agreement (as hereinafter defined) with Helsinn Healthcare SA, Via Pian Scairolo, 6912, Pazzallo, Switzerland (hereinafter called "HHC") by means of which MGI has been licensed with the right to distribute, promote, market and sell the Products (as hereinafter defined) in the Territory and has undertaken to purchase the Products exclusively from a source indicated or approved in writing by HHC.

b. HBP carries on business as a pharmaceutical manufacturer and trader and, in particular for the purpose of this Agreement, represents that it has been duly appointed by HHC as the supplier of the Products to MGI for the purpose of the sale of said Products by MGI.

c. The Parties agree that this preamble constitutes an integral part of this Agreement and all capitalized terms used in this preamble shall have the meaning as defined in Article 1 hereafter.

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants and conditions herein contained, the Parties hereby agree as follows:

ARTICLE 1- DEFINITIONS

The Following terms as used in this Agreement have, unless the context clearly indicates otherwise, the following meanings:

1.1 "Accounting Period" means the quarters ending 31st March, 30th June, 30th September and 31st December in each year throughout the term of this Agreement.

1.2 "Affiliate" means an organization that, whether now or in the future, controls. is controlled by or is under common control with a Party. For the purposes of this definition, the terms "controls," "controlled by," and "under common control with" as used with respect to any Party, means the possession (directly or indirectly) of fifty percent or more of the voting stock or other equity interest of a subject entity with the power to vote, or the power in fact to control the management decisions of such entity through the ownership of securities, by contract or otherwise.

1.3 "Compound" means the active pharmaceutical ingredient (3aS-2-[(S)-I-Azabicyclo[2.2.2]oct-3-yl]-2,3, 3a,4,5,6-hexahydro-l-oxo-IH-benzidelisoquinoline hydrochloride, having the genetic name palonosetron hydrochloride (INN) For use in human medicine.

1.4 "FDA" means the U.S. Food and Drug Administration or any successor agency.

1.5 "License Agreement" means the license agreement entered into between MGI and HHC on April 6th, 2001 granting MGI the exclusive right to distribute, market and sell the Products in the Territory.

1.6 "Net Sale Price" means the gross sale price in local currencies of the Products in the Territory by MGI and/or its Affiliates, including any local Affiliate in Canada, for arm's lenghth sales to any non-Affiliated third party less those normal and customary deductions made under Generally Accepted Accounting Principles to arrive at Product sales. Such deductions shall comprise any trade and quantity discounts, returns and allowances, rebates, cash discounts, sales and excise taxes, transportation and insurance charges, chargebacks and other amounts paid on sale or distribution of Product, provided that such deductions (i) are directly linked to and related to the gross sales invoiced amount, (ii) are specifically related to commercial policies having the purpose of acquiring, maintaining and maximising sales and enlarging the market share of the Product, (iii) do not exceed the average usual and customary deductions of this kind for similar products in the Field (as such term is defined in the Licence Agreement) in the Territory and (iv) shall not include any mark-up or other increase over costs actually incurred by MGI and/or its Affiliates in connection with such gross

sales. It is understood that said deductions shall not include any amount related to bad or doubtful debts. Where (a) a Product is sold as one of a number of items (bundled transaction) without a separate price; or (b) the consideration for the Product shall include any non-cash element; or (c) the Product shall be transferred in any manner other than an invoiced sale, the Net Sales applicable to the quantity of Product of any such transaction shall be deemed to be the average Net Sales for all other transactions of Product at that time in the Territory.

1.7 "Net Sales" means the gross sales in local currencies of all Products sold in the Territory by MGI and/or its Affiliates, including any local Affiliate in Canada, for arm's lenghth sales to any non-Affiliated third party less those normal and customary deductions made under Generally Accepted Accounting Principles to arrive at Product sales. Such deductions shall comprise any trade and quantity discounts, returns and allowances, rebates, cash discounts, sales and excise taxes, transportation and insurance charges, chargebacks and other amounts paid on sale or distribution of Product, provided that such deductions (i) are directly linked to and related to the gross sales invoiced amount, (ii) are specifically related to commercial policies having the purpose of acquiring, maintaining and maximising sales and enlarging the market share of the Product, (iii) do not exceed the average usual and customary deductions of this kind for similar products in the Field (as such term is defined in the Licence Agreement) in the Territory and (iv) shall not include any mark-up or other increase over costs actually incurred by MGI and/or its Affiliates in connection with such gross sales. It is understood that said deductions shall not include any amount related to bad or doubtful debts.

Where (a) a Product is sold as one of a number of items (bundled transaction) without a separate price; or (b) the consideration for the Product shall include any non-cash element; or (c) the Product shall be transferred in any manner other than an invoiced sale, the Net Sales applicable to the quantity of Product of any such transaction shall be deemed to be the average Net Sales for all other transactions of Product at that time in the Territory.

1.8 "Parties" means HBP and MGI and "Party" means either of them as the context indicates.

1.9 "Products" means the pharmaceutical preparations for human use in I.V. dosage form, containing the Compound as an active ingredient, in the formulation which will he described in the Registration. The current formulation as submitted to the Food and Drug Administration of the United States of America in the IND 39,797 Amendment # 64 and to the Therapeutic Products Programme of Canada in the IND 9427-H0836-21C is described in the First Appendix hereto.

1.10 "Registration" means any official approval, or authorization by the competent regulatory authorities, which is legally required to lawfully market the Products in the Territory, including, without limitation, any governmental price approval or reimbursement approved under a national health insurance system.

1.11 "Syntex Agreement" means a license agreement between HHC and Syntex (U.S.A.) LLC dated 23rd June 1998 by means of which HHC in-licensed world-wide rights on the Compound and Products.

1.12 "Territory" means the United States of America and its possessions arid territories (Puerto

Rico, United States Virgin Islands), and Canada and as provinces, possessions and territories.

ARTICLE 2 - PURCHASE OF PRODUCTS

2.1 Throughout the Term of this Agreement, and subject to the terms and conditions contained herein, MGI undertakes to purchase exclusively from HBP, and HBP undertakes to sell to MGI, MGI's entire requirements of the Products to be distributed, promoted, marketed and sold by MGI or MGI's Affiliates under the License Agreement.

2.2 MGI shall not use the Products for any other purpose than distributing, promoting, marketing and selling said Products in accordance with the terms and conditions of the License Agreement.

ARTICLE 3 - PRICE AND TERMS OF PAYMENT

3.1 The price of the Products purchased by MGI hereunder is as set forth in the Second Appendix hereto. At the fifth and at any following anniversary of the launch of the Product in the United States of America by MGI, the minimum supply price of the Products as indicated in the Second Appendix hereto shall be revised in accordance with the total percentage change in the price of pharmaceuticals products as reflected in the Pharmaceutical Price Index over the twelve month period preceding each said anniversary date.

3.2 Any payment by MGI for the delivered Products shall be effected by wire transfer of immediately available funds to an account designated in writing by HBP in United States Dollars within 30 (thirty) days from the date of receipt of the invoice (which shall be deemed to have been received on the date following the date of delivery to MGI by telefax) and be deemed paid

when freely received. MGI shall bear all costs in connection with effecting payments.

3.3 MGI shall in no case be entitled to off set or otherwise withhold any payment due to HBP in view of possible, justified or unjustified, claims against HBP.

3.4 In the event that, at any time throughout the term of this Agreement, MGI fails to pay for the supply of Products in accordance with the terms and conditions contained herein, and without prejudice to HBP's right to terminate this Agreement as per article 12.1 hereunder, MGI shall, at HBP's request, cause to be delivered to HBP a confirmed letter of credit from a primary international bank on terms and conditions reasonably satisfactory to HBP securing the payment obligations from MGI to HBP under this Agreement in connection with the following order of Products (the "Letter of Credit"). The Letter of Credit shall be irrevocable without the prior written consent of HBP. In the absence of such Letter of Credit, HBP shall be relieved from its obligation to supply the Products to MGI hereunder.

ARTICLE 4 - FORECASTS, ORDERS AND TERMS OF DELIVERY

4.1 MGI shall, prior to September 30th in each year throughout the term of this Agreement, supply HBP in writing with a purchase forecast for the Products for each Accounting Period of the following calendar year. Any such forecast shall be deemed to be a binding order by MGI for the first Accounting Period of such year. Moreover MGI shall issue its firm orders relevant to the three following Accounting Periods at least 90 (ninety) days in advance of the requested delivery date and, at each rime, it shall supply HBP

with its purchase forecast relevant to a further calendar year so as to maintain at all times a rolling twelve-month purchase forecast and shall promptly notify HBP of any projected changes thereto.

4.2 The Products will be supplied to MGI only against MGI's written order and all orders shall be subject to written acceptance and confirmation by HBP before becoming binding. Such acceptance and confirmation may be by facsimile or otherwise. Each order by MGI shall be for a minimum quantity corresponding to the sire of one production hatch of Products, as shall be indicated in due time by HBP, or multiples thereof.

HBP shall use commercially reasonable efforts to execute all orders received and accepted pursuant to this Article within 90 (ninety) days from the date of receipt of the relevant order by HBP. MGI's firm orders shall be at least 80% (eighty percent) and not more than 120% (one hundred and twenty percent) of its forecast of Products for the applicable Accounting Period as per Article 4.1 hereabove. HBP shall not be obliged to supply more than 100% (one hundred percent) of MGI's initial forecast of Products within the applicable Accounting Period. However, in the event that, in any Accounting Period, MGI's orders are more than 100% (one hundred percent) of the relevant forecasts. HBP agrees to use commercially reasonable efforts to supply MGI with amounts in excess of MGI's forecast of Product during said Accounting Period, on condition however that this shall not hamper, delay or otherwise prejudice supplies of Products to any other of HBP's customers. MGI shall keep throughout the term of this Agreement a stock of Products adequate to meet market demand and to cover possible shortages in the supplies of Products, such stock to

approximately correspond at least to three-month average sales. In turn, HBP undertakes to keep throughout the term of this Agreement a stock of Products in semi-finished form (i.e. vials without final packaging) approximately corresponding to at least to two-month average sales.

4.3 Any purchase order or acknowledgement thereof, whether printed, stamped, typed or written, shall be governed by the terms and conditions of this Agreement and none of the provisions of such purchase order or acknowledgement thereof shall he applicable, except those specifying quantity ordered, delivery dates and invoice information, and with respect to those specifications only to the extent that they are in compliance with the terms and conditions of this Agreement. To the extent there is any discrepancy between this Agreement and any purchase order or acknowledgement thereof, this Agreement will control.

4.4 All orders of Products shall be delivered DDU (Incoterms 2000) MGI's or MGI nominees warehouse in the United States of America. unless otherwise agreed in writing by the Parties. MGI shall be solely responsible for all customs clearance of, and import/export regulations for, the Products and it shall hear and pay all taxes, duties, levies and other charges imposed by reason of its purchase, import and resale of the Products.

4.5 If, for any reason, HBP is unable to supply MGI's firm orders for the Products up to the forecasted level, or is unable to supply such quantities in a manner meeting the Specifications, during any ninety (90) day period, the Parties shall promptly meet to discuss the reasons for such failure to supply, and HBP shall thereafter designate a third party

manufacturer to manufacture the Products. HBP shall provide to such third party manufacturer, appropriate manufacturing licenses and reasonable technical assistance to enable it to manufacture the Products, in a manner that minimizes disruption to MGI of Product supply.

ARTICLE 5 - QUALITY

5.1 HBP shall manufacture, or shall cause the Products to be manufactured, in accordance with applicable current Good Manufacturing Practice and with applicable specifications.

5.2 Each batch of Products shall be delivered to MGI accompanied by appropriate certificates of analysis, attesting the compliance of each relevant batch with the specifications for said Products as the same are contained in the Registration of the Products. MGI shall carry out appropriate visual inspection of the Products, as well as any other analysis which MGI may deem appropriate or necessary, upon receipt. Should it occur that any batch of Products does not meet said approved specifications, MGI shall, as soon as possible and in any case within 30 (thirty) days after receipt of the Products, give notice in wilting to HBP specifying in detail the claimed non-conforming characteristics of the Products. In the absence of MGI's notification within the said term, MGI shall be deemed to have accepted such Products. Should HBP recognize that such Products delivered to MGI do not meet the approved specifications, and provided MGI demonstrates that the Products have been properly handled and stored after delivery, HBP shall replace, at its own cost, such Products. Such replacement shall be done, to the extent possible, in accordance with the timing reasonably agreed among the Parties which, in any

event, shall be as soon as reasonably possible thereafter. It is understood and agreed that HBP's total responsibilities hereunder shall he limited to said replacement of Products. Should HBP not he in agreement with MGI's claim of defect, a sample of the alleged defective Products shall be submitted for analysis to an independent laboratory to be agreed in good faith between MGI and HBP in writing. The decision of such laboratory shall be final and binding for both MGI and HBP and the corresponding expenses will be paid by the Party found to be in error.

5.3 HBP shall at any time be free to determine the manufacturer and the place of manufacture of the Products, subject however to applicable laws and regulations and to compliance with the License Agreement. In no event shall MGI be entitled to manufacture any Products by virtue of this Agreement.

5.4 MGI shall store and distribute, and shall cause the Products to be stored and distributed, according to applicable current Good Manufacturing Practice or any other applicable laws and regulations. MGI shall permit HBP's representatives, during normal business hours and upon three business days advance notice in writing hut not more than once a year or as otherwise reasonably requested by HBP, to inspect those areas of the warehouses of MGI, its Affiliates and its distributors where the Products are inspected, analyzed or stored, for the purpose of verifying compliance with applicable laws and regulations as well as with this Agreement. Such inspection shall include, without limitation, the right to examine any relevant internal procedures or records of MGI, its Affiliates and distributors. MGI shall give and shall cause its Affiliates and distributors to give, all

necessary assistance for a full and correct carrying out of the inspection by HBP. No such inspection by HBP shall relieve MGI, its Affiliates and distributors of any of their obligations under this Agreement in any way whatsoever.

5.5 The Products shall be supplied by HBP or HBP's nominee to MGI in a secondary package inclusive of leaflet, ready for distribution. Artwork and all necessary films for printing packs, package inserts, leaflets and labels will be prepared and supplied by MGI, at its expenses, based upon indications, box design and measurements provided by HBP. Any change shall have to be communicated by MGI to HBP at least 6 (six) months in advance of its enforcement. The costs relevant to the change, including costs relevant to repackaging or disposal of Products in stock at HBP, (i) shall be entirely borne by MGI if the change has been requested by MGI, and (ii) shall be shared between the parties in case the change is required by any regulatory authority or is jointly deemed advisable by the Parties.

5.6 Events concerning Product recall, complaint, field alert or Product withdrawal relevant to the Products marketed by MGI in the Territory shall be governed by the procedures and rules established in the Licence Agreement.

ARTICLE 6 - RECORDS AND REPORTS

6.1 MGI shall submit to HBP at the end of each Accounting Period a written statement signed by a responsible officer of MGI which shall show the units of Products sold or otherwise disposed of by MGI, the gross sale price and the Net Sale Price of the Products and any change thereof, together with a detailed listing and appropriate evidence of any and all

discounts granted for each client, wholesaler and/or distributor as necessary to permit to HBP to calculate and verify the supply price of the Products as per the Second Appendix hereto, the gross sales and the Net Sales for said Accounting Period and the existing stock of Products in MGI's, its Affiliates' and its distributors' warehouses. Throughout the term of this Agreement and for a period of at least 3 (three) years thereafter, MGI shall keep complete and accurate hooks. records and accounts in accordance with sound accounting practice covering all its operations hereunder as necessary to determine and verify the units of Products sold or otherwise disposed of by MGI, the Net Sale Price of the Products, the Net Sales for each Accounting Period, and any change thereof. HBP shall have the right, at any time throughout the term of this Agreement and for a period of three years thereafter, during normal business hours and upon at least three (3) business days advance notice, to have such books, records and accounts inspected and audited by its duly authorized representatives or, at HBP's discretion, by an independent certified public accountant to be nominated by HBP and reasonably acceptable to MGI. MGI shall fully co-operate with HBP, its authorized representatives or independent certified public accountant and make available all work papers and other information reasonably requested in connection herewith. In the event the inspection or audit reveals that an underpayment has occurred, MGI shall immediately pay to HBP any underpaid amount within 10 (ten) days of the date HBP delivers to MGI the relevant inspection or audit report. In case of an underpayment of at least five percent (5%) of the amounts owing during the audited period, MGI shall also bear all the costs of the inspection or audit and any overdue amounts hereunder shall bear interest at

the prime rate applicable in Switzerland as of the date such payment was originally due.

6.2 Each of the Parties hereby agrees that any and all communications sent to or received from the other Parry hereunder, including but not limited to those described at Article 13.2 hereunder, shall he immediately sent in copy by telefax to HHC.

ARTICLE 7- REPRESENTATIONS AND WARRANTIES

7.1 HOP hereby represents and warrants to MGI as follows:

7.1.1 HBP has beets duly organized and is validly existing as a corporation in good standing under the laws of the Republic of Ireland. HBP has the corporate power and authority to enter into this Agreement and to consummate the transactions contemplated by this Agreement.

7.1.2 The execution, delivery and performance of this Agreement, and the consummation of the transactions contemplated by this Agreement, by HBP have been duly and validly authorized by all requisite corporate actions. This Agreement constitutes a legal, valid and binding agreement of HBP enforceable against HBP in accordance with its terms.

7.1.3 The execution, delivery and performance by HBP of this Agreement requires no action by or in respect of, or consent or approval of, or filing with, any Governmental Authority.

7.1.4 The execution, delivery and performance by HBP of the contemplated transactions do not and will not (A) contravene or conflict with the charter or bylaws or HBP, as applicable, (B) contravene or conflict with or constitute a violation of any provisions

of any applicable law binding upon HBP, or (C) constitute a default in any material respect under or give rise to any right of termination, cancellation or acceleration of, any agreement or instrument to which HBP is a party, or to a loss of any material benefit to which HBP is entitled.

7.1.5 There is no action, suit, investigation or proceeding pending against, or to the knowledge of HBP, threatened against or affecting, HBP before any court, arbitrator or any governmental authority, including but not limited to Regulatory Authorities, that in any manner challenges or seeks to prevent, enjoin, alter or materially delay the contemplated transactions, and, to the knowledge of HBP, there is no reasonably valid basis for any such action, suit, investigation or proceeding to be brought.

7.1.6 The persons executing this Agreement on behalf of HBP are duly authorized to do so and by so doing have bound HBP to the terms and conditions of this Agreement.

7.1.7 HBP has been duly authorized and entrusted by HHC to supply the Products to MGI.

7.2 MGI hereby represents and warrants to HBP as follows:

7.2.1 MGI is a corporation duly incorporated, validly existing and in good standing under the laws of the state of its incorporation and has all corporate powers and all governmental licenses, authorizations, consents and approvals required to carry on its business as now conducted and as contemplated to be conducted in connection with the transactions contemplated by this Agreement (the "Contemplated Transactions"). MGI is duly qualified to do business as a foreign corporation in each jurisdiction where the

character of the property owned or leased by it or the nature of its activities (after giving effect to the Contemplated Transactions) make such qualification necessary to carry on its business, except where the failure to so qualify would not have a material adverse effect on MGI.

7.2.2 The execution, delivery and performance by MGI of this Agreement and the consummation by MGI of the Contemplated Transactions are within the corporate powers of MGI, and have been duly authorized by all necessary corporate action on the part of MGI. This Agreement constitutes a legal, valid and binding agreement of MGI, enforceable against MGI as applicable in accordance with its terms.

7.2.3 The execution, delivery and performance by MGI of this Agreement requires no action by or in respect of, or consent or approval of. or filing with, any Governmental Authority, other than filings with the SEC in fulfillment of MGI's disclosure obligations under U.S. securities laws.

7.2.4 The execution, delivery and performance by MGI of the Contemplated Transactions do not and will not (A) contravene or conflict with the charter or bylaws of MGI, as applicable, (B) contravene or conflict with or constitute a violation of any provisions of any Applicable Law binding upon MGI, or (C) constitute a default in any material respect under or give rise to any right of termination, cancellation or acceleration of, any agreement or instrument to which MGI is a party, or to a loss of any material benefit to which MGI is entitled.

7.2.5 There is no action, suit, investigation or proceeding pending against, or to the knowledge of MGI, threatened against or affecting, MGI before any

court, arbitrator or any governmental authority, including but not limited to regulatory authorities, that in any manner challenges or seeks to prevent, enjoin, alter or materially delay the Contemplated Transactions, and, to the knowledge of MGI, there is no reasonably valid basis for any such action, suit investigation or proceeding to he brought.

7.2.6 The persons executing this Agreement on behalf of MGI are duly authorized to do so and by so doing have bound MGI to the terms and conditions of this Agreement.

ARTICLE 8 - LIABILITIES, INDEMNITIES AND INSURANCE

8.1 MGI shall be fully liable for and shall defend, indemnify and hold HBP and its Affiliates, officers, directors and employees wholly free and harmless from and against any and all liabilities, damages, losses, costs, taxes, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgements or administrative and judicial orders arising out of or resulting front any claim, suit or proceeding to the extent arising out of or resulting from (a) any failure by MGI, its local distributors or Affiliates to comply with any applicable laws, regulations and/or administrative decision regarding the Products; (b) the storage. distribution, sampling, record-keeping, analysis, transfer or sale of the Products; (c) the promotion, advertising and marketing of the Products; (d) the failure of any Products supplied hereunder to comply with the applicable approved specifications that (i) could have been detected by MGI carrying out visual inspection on the supplied Products with ordinary diligence or (ii) results from any Products which have been altered, changed, packed or re-

packed, processed or otherwise treated other than in strict accordance with HBP's instructions and specifications; or (e) any negligent or wrongful act or omission and/or any breach by MGI or by any of its local distributors and/or Affiliates of any of MGI's obligations, representations and/or warranties hereunder.

8.2 HBP shall be liable for and shall defend, indemnify and hold MGI and its Affiliates, officers, directors and employees free and harmless from and against any and all liabilities, damages, losses, costs, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgments or administrative and judicial orders, arising out of or in any way resulting from any claim, suit or proceeding to the extent arising out of or resulting from (a) failure of any Products supplied hereunder to conform to the applicable approved specifications, excluding however any liabilities, losses, damages, costs, expenses claims, demands, suits, penalties, judgments or orders resulting from any such non-compliance that (i) could have been detected by MGI carrying out visual inspections on the supplied Products with ordinary diligence or (ii) results from any Products which have been altered, changed, packed or re-packed, processed or otherwise treated other than in strict accordance with HBP's instructions and specifications; or (b) any negligent or wrongful act or omission and/or breach by HBP of any of its obligations and/or warranties hereunder.

8.3 Being understood that each of the Parties hereto shall take all reasonable steps to avoid or mitigate any loss, damage or liability which might give rise to a claim under this Agreement, a Party seeking

indemnification pursuant to this Article 8 (an "Indemnified Party") shall give prompt and full written notice to the Party from whom such indemnification is sought (the "Indemnifying Party") of the assertion of any claim, or the commencement of any action, suit or proceeding in respect of which indemnity is or may he sought hereunder, provided however that no failure to give such notice or co-operation shall relieve the Indemnifying Party of any liability and/or obligation hereunder (except to the extent the Indemnifying Party has suffered actual prejudice thereby). Subject to any right of Syntex (U.S.A.) LLC under the Syntex Agreement, the Indemnifying Party shall have the sole right to control the defense and settlement thereof. The Indemnified Party will give the Indemnifying Party such information with respect thereto as the Indemnifying Party may reasonably request and will co-operate with the Indemnifying Patty in the defense of said claim, suit or proceeding as the Indemnifying Party may reasonably request. The Indemnified Patty shall not, except at its own cost, voluntarily make any payment or incur any expense with respect to any claim, suit or proceeding without the prior written consent of the Indemnifying Party. In addition, the Indemnifying Party shall be subrogated to the rights of the Indemnified Party against any third party, and such Indemnified Party hereby assigns to the Indemnifying Party all claims, causes of action and other rights which the Indemnified Party may then have against any third party, including Affiliates and, in the case of HBP, against any contract manufacturer of the Products, with respect to the claim, suit or proceeding which is the subject of the claim for indemnification hereunder. Conversely, and without in any way limiting the obligation of either Party to indemnify the other Party

as herein provided, to the extent that either Party shall fail to perform its indemnification obligations under this Article 8, such Party owing a duty of indemnification hereby assigns to the other Party all claims, cause of action and other rights which the Party owing such duty may then have against any third party, including Affiliates and, in the case of HBP, against any contract manufacturer of the Products, with respect to the claim, suit or proceeding.

8.4 MGI shall be solely responsible towards its customers for handling all matters concerning the Products, subject to cooperation with HBP on any recall or other matters that may be injurious to HBP. MGI shall be responsible for any expired Products, whether stored by MGI and/or its local distributors or returned by wholesalers, pharmacists, doctors, hospitals to whom said Products have been sold. HBP shall (i) reimburse to MGI documented reasonable costs incurred by MGI with regard to the destruction of expired Products, up to a maximum quantity of 1% (one percent) of the units of Products sold by MGI in any calendar year and (ii) replace free of charge said expired Products, up to a maximum quantity of 1% (one percent) of the units of Products sold by MGI in any calendar year. Except as provided hereabove, MGI shall not be entitled to any replacement of Products nor to any compensation of any kind from HBP in connection herewith. MGI shall indemnify, defend and hold HBP and its Affiliates, directors, officers and employees wholly free and harmless from and against any and all liabilities, damages, losses, costs, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgments or administrative and judicial orders arising therefrom; except with respect to any recall or other regulatory action arising

from any breach by HBP or its Affiliates of any warranty, representation or other material obligation contained in this Agreement or the negligence or willful misconduct of HBP or its Affiliates.

8.5 Each Party shall indemnify and hold the other Party wholly harmless from and against any and all liabilities, damages, losses, costs, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgments or administrative and judicial orders arising out of any behavior contrary or in excess to the provisions of Article 13.1 hereunder.

8.6 THE SOLE REPRESENTATIONS AND WARRANTIES THAT HBP MAKES WITH RESPECT TO THE MATTER CONTEMPLATED BY THIS AGREEMENT ARE EXPRESSLY SET FORTH IN ARTICLE 7.1. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, HBP MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, OF MARKETABILITY, CAPACITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCTS. NO ORAL OR WRITTEN REPRESENTATION BY OR ON BEHALF OF HBP SHALL BE INTERPRETED TO CONTAIN ANY SUCH WARRANTY. NEITHER MGI NOR ANY OF ITS EMPLOYEES OR REPRESENTATIVES IS AUTHORISED TO GIVE ANY WARRANTIES OR MAKE ANY REPRESENTATION ON BEHALF OF HBP.

8.7 THE SOLE REPRESENTATIONS AND WARRANTIES THAT MGI MAKES WITH RESPECT TO THE MATTER CONTEMPLATED BY THIS AGREEMENT ARE EXPRESSLY SET FORTH IN ARTICLE 7.2. AND MGI HEREBY DISCLAIMS ALL OTHER REPRESENTATIONS OR WARRANTIES

OF ANY KIND, EXPRESS OR IMPLIED. NO ORAL OR WRITTEN REPRESENTATION BY OR ON BEHALF OF MGI SHALL BE INTERPRETED TO CONTAIN ANY SUCH WARRANTY. NEITHER HBP NOR ANY OF ITS EMPLOYEES OR REPRESENTATIVES IS AUTHORISED TO GIVE ANY WARRANTIES OR MAKE ANY REPRESENTATION ON BEHALF OF MGI.

8.8 NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, NEITHER OF THE PARTIES SHALL BE LIABLE TOWARDS THE OTHER FOR INDIRECT, SPECIAL, PUNITIVE EXEMPLARY, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION LOSS OF PROFITS OR REVENUES. REGARDLESS OF WHETHER SUCH DAMAGES WERE FORESEEABLE OR NOT. THIS CLAUSE WILL HOWEVER NOT BE APPLICABLE IN CASE OF BREACH BY MGI OF THE PURCHASE OBLIGATIONS STATED AT ARTICLE 2 AND BREACH BY EITHER PARTY OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS STATED AT ARTICLE 9 OF THIS AGREEMENT.

of this Agreement on all policies of general commercial liability insurance and product liability insurance covering MGI, which coverage shall, when MGI either initiates clinical trials on the Products or begins marketing or distributing the Products for commercial sale or for promotional purposes, have limits of liability which are commercially reasonable in the Territory but shall he not less than USD 30,000,000 (United States Dollars thirty million) per loss occurrence. Within 5 (five) days of the Effective Date and of each beginning of each policy period, MGI shall provide HBP with a certificate evidencing the coverage

required hereby and the amount thereof. Such coverage shall be with a reputable insurance company having at least an A.M. Best "A" rating and shall have to be maintained for not less than 6 (six) years following expiration or termination of this Agreement for any reason or if such coverage is of the "claims made" type, for ten years following expiration or termination of this Agreement for any reason.

ARTICLE 9 - CONFIDENTIALITY

9.1 MGI shall treat as strictly confidential, and shall use solely for the purpose of and in accordance with this Agreement, any and all information, data and/or document received hereunder or in connection with the Contemplated Transaction not generally known to the trade (all hereinafter referred to as the "Confidential Information"). MGI shall not make such Confidential Information available to any third Party, including any of its Affiliates, except to competent government agencies to which it will be necessary to disclose such Information, and in this case (a) strictly to the extent requested by said agencies and (b) only upon exercise of its best efforts to cause said agencies to maintain confidentiality thereof.

9.2 Such Confidential information shall only he made available to such employees of MGI who are directly and necessarily involved in the authorized use of Confidential information and who are subject to a secrecy obligation by contract, to the extent strictly necessary to perform their duties and obligations hereunder.

9.3 Notwithstanding expiration or termination of this Agreement for any reason, these confidentiality and non-use obligations shall continue until the Confidential Information has become generally known

to the public, provided however that nothing contained herein shall in any way restrict or impair the right of MGI to use, disclose or otherwise deal with Information which MGI can demonstrate to HBP by clearly convincing documentation.

9.3.1 is or hereafter becomes part of the public domain through no act or omission of MGI, its employees, Affiliates and/or local distributors, or

9.3.2 MGI was in lawful possession of prior to receipt of the Confidential Information from HBP, or

9.3.3 previously was, or at any time hereafter is, received in good faith by MGI from sources other than HBP and/or HHC and which did not originate, directly or indirectly, from Syntex. or

9.3.4 at the time of disclosure, was known by MGI or an Affiliate or local distributor, or after disclosure was independently developed by MGI, an Affiliate or local distributor without use of the Confidential Information.

9.4 HBP shall keep strictly confidential, in the same way mutatis mutandis as provided here above for MGI in respect of Confidential Information, any MGI Confidential Information (as defined herein) received from MGI hereunder, except as otherwise specifically provided in this Agreement. As used herein, the term "Confidential Information" shall mean all information disclosed by MGI to HBP relating to the markets, customers, suppliers, patents or patent applications, inventions, know-how, data or information, products, research and development, procedures, designs, formulas, business plans, financial projections, employees, consultants or any other similar aspects MGI's present or future business, whether such

information is disclosed in written, oral, electronic, graphic or other format.

ARTICLE 10 - FORCE MAJEURE

10.1 Except as set forth in Section 4.5, if the performance of this Agreement is prevented or restricted by government action, war, fire, explosion, flood, strike, lockout, embargo, act of God, or any other similar cause beyond the control of the defaulting Party, the Party so affected shall be released for the duration of the force majeure, or such other period agreed between the Parties as being reasonable in all circumstances, from its contractual obligations directly affected by the force majeure, provided that the Party concerned shall:

10.1.1 give prompt notice in writing to the other Party of the cause of force majeure;

10.1.2 use all best endeavors to avoid or remove such cause of non-performance:

10.1.3 continue the full performance of this Agreement as soon as such cause is removed.

10.2 The Parties shall take all reasonable steps to minimize the effects of force majeure on the performance of this Agreement and shall, if necessary, agree on appropriate measures to be taken. Should the force majeure continue for more than 6 (six) months, then the other Party shall have the right to terminate this Agreement forthwith.

10.3 Notwithstanding anything contained in this Article 10, obligations to pay money accruing prior to the force majeure event are never excused by force majeure.

ARTICLE 11 - TERM

11.1 This Agreement comes into force at the Effective Date hereof. Unless terminated earlier pursuant to the provisions hereof, it shall terminate automatically at termination or expiration for any reason of the License Agreement.

ARTICLE 12 - TERMINATION

12.1 Each of the Parties reserves the right to terminate this Agreement in case of any substantial or persistent breach of any of the terms and conditions of this Agreement by the other Party. The defaulting Party shall be given in writing a 60 (sixty)-day period, except as otherwise specifically provided, to fulfill its obligations hereunder and, if after such period it is still in breach of the Agreement, the other Party shall have the right to terminate this Agreement by written notice to the defaulting Party. In the event of a breach by MOI of any of the terms and conditions of this Agreement entitling HBP to terminate this Agreement under this Article 12.1, HBP shall immediately and fully inform HHC in writing for appropriate actions by HHC. In particular, MOI hereby acknowledges and agrees that termination of this Agreement by HBP pursuant to this Article 12.1 shall entitle HHC to terminate the License Agreement.

12.2 Either Party shall have the right to terminate this Agreement upon written notice to the other Party, if such other Party shall become insolvent or shall make an assignment for the benefit of creditors or become involved in receivership, bankruptcy or other insolvency or debtor relief proceedings, or any similar proceedings, or in proceedings. voluntary or forced, whereby the Party involved is limited in the free and

unrestrained exercise of its own judgment as to the carrying out of the terms of this Agreement.

12.3 HBP shall have the right to terminate this Agreement by written notice to MOI if MOI infringes the confidentiality and/or non-use obligations provided for in Article 9 hereabove. MOI shall have the right to terminate this agreement by written notice to HBP if HBP breaches the confidentiality and/or non-use obligations provided for in Article 9.4 hereabove.

12.4 Without limiting the generality of the foregoing, termination or expiration of this Agreement for any reason shall not extinguish any existing claims either of the Parties may have for indemnification and shall not preclude either of the Parties from pursuing any claim for indemnification such Party otherwise may have to the extent that the circumstances giving rise to such claim arose prior to, on or after the date of termination or expiration.

12.5 Upon expiration or termination of this Agreement for any reason, MOI shall promptly terminate using any and all information and data received hereunder and return or deliver all such materials to HBP without retaining copies, notes, summaries or translations thereof.

12.6 Unless otherwise set forth herein, the Parties' remedies under this Agreement are intended to he cumulative and not mutually exclusive.

ARTICLE 13 - MISCELLANEOUS

13.1 Independent contractor status

The status of HBP and MGI under the business arrangement established by this Agreement is that of independent contractors. MGI shall perform as an independent contractor in relation to both HBP and

MGIs customers and, accordingly, MGI shall purchase the Products from HBP or HBP's nominee and resell them to its customers in its own name and for its own account. MGI has no authority whatsoever to act as an agent or representative of HBP nor any authority or power to contract in the name of or create any liability against or otherwise bind HBP in any way for any purpose, nor shall HBP have such authority or power to so bind MGI.

13.2 Notices

All reports, notices and communications given or made pursuant to this Agreement by one Party to the other shall be validly given or made for all purposes, in the absence of acknowledgement of receipt, on the date of mailing if mailed by registered airmail or by international courier to the addressee Party at the following addresses, respectively:

HELSINN BIREX PHARMACEUTICALS LTD.
Damastown
Mulhuddart
Dublin 15
Republic of Ireland
For the attention of: General Manager

With copy to:
HELSINN HEALTHCARE SA
P.O. B0X 357
6915 Pambio-Noranco
SWITZERLAND
For the attention of Legal Department

MGI PHARMA INC.
6300 West Old Shakopee Road
Suite 110
Bloomington
MN 55435-2318. USA

For the attention of: Manager, Legal Affairs

With copy to:
Dorsey & Whitney LIP
220 South Sixth Street
Minneapolis, MN 55402
For the attention of: Timothy S. Hearn

13.3 Binding Effect

Subject to the provisions of article 13.6 herein, this Agreement shall inure to the benefit of, and be binding upon, the respective successors of the Parties.

13.4 Waiver

The failure of a Party to insist upon strict performance of any of the terms and conditions of this Agreement by the other Party shall not constitute a waiver of any of the provisions hereof and no waiver by a Party of any of said term and conditions shall be deemed to have been made unless expressed in writing and signed by such waiving Party.

13.5 Interpretation

13.5.1 The language of this Agreement is English. No translation into any other language shall be taken into account in the interpretation of the Agreement itself.

13.5.2 The headings in this Agreement are inserted for convenience only and shall not affect its construction.

13.5.3 Where appropriate, the terms defined in Article 1 hereabove and denoting a singular number only shall include the plural and vice versa.

13.5.4 References to any law, regulation, statute or statutory provision includes a reference to the law,

regulation, stature or statutory provision as from time to time amended. extended or re-enacted.

13.6 Assignment

This Agreement cannot be transferred. sublicensed, assigned or otherwise disposed of (by operation of law or otherwise) by MOI without the prior, written authorization of HBP, which authorization shall not be unreasonably withheld, provided however that MOI shall he entitled to assign this Agreement in conjunction with the assignment of the License Agreement in accordance with the terms and conditions thereof. HBP shall have the right to assign or transfer, in whole or in part, this Agreement to any of its Affiliates

13.7 Statements to the Public

Neither HBP nor MOI shall make or procure or permit the making of any announcement or statement to the public with respect to this Agreement, its subject matter or any ancillary matter without the prior consent of the other Party, which consent shall not be unreasonably withheld.

The wording and the timing of any press release or of any other announcement and/or statement to the public shall have to be agreed upon in advance between the Parties.

Nothing herein shall prohibit MOI from disclosing information to the extent required by the U.S. Securities and Exchange Commission, Nasdaq or other similar authorities. It is however understood and agreed that (a) the contents of any copy of this Agreement, or of tiny other agreement between the Parties, which has to be sent to the SEC shall have to be previously agreed upon between the Parties and shall be in redacted form to maintain the

confidentiality of proprietary and/or competitivity sensitive information, and (b) MOI shall use its best efforts to obtain authorization by the SEC to keep confidential any information which is deemed to be confidential by the Parties or any of them or which may, in either Party's opinion, put a competitive advantage to third parties.

13.8 Expenses

Unless specifically and expressly provided for to the contrary in this Agreement, each of the Parties shall hear its own expenses incurred in connection with the performance of this Agreement.

13.9 Survival

The following provisions shall survive expiration or termination of this Agreement for any reason: Articles 1 (whole clause), 6 (whole clause), 8 (whole clause), 9 (whole clause), 12.4 through 12.6, 13 (whole clause), 15 (whole clause) and 16 (whole clause).

ARTICLE 14 - APPENDICES

14.1 The following Appendices shall he an integral part of this Agreement:

Appendix I: Products

Appendix 2: Price

ARTICLE 15 - LAW TO GOVERN AND ARBITRATION

15.1 This Agreement shall be governed by and construed in accordance with the law of Switzerland.

15.2 It is the express decision of the Parties that any dispute which may arise between the Parties concerning this Agreement, which cannot be settled amicably, shall be submitted to arbitration for final

decision. Also, any dispute as to the applicability of the arbitration clause shall be subject to arbitration. Notwithstanding the above, each Party expressly reserves the right to seek judicial relief from a court of competent jurisdiction if the other Party is or appears to be in violation of such other Party's obligations of non-use and non-disclosure under Article 9 above, including. without limitation, any injunction or other preliminary relief.

15.3 It is expressly agreed that arbitration shall be held in English language in Geneva (Switzerland) and conducted under the Rules of Arbitration of the International Chamber of Commerce. The court of arbitration shall consist of three arbitrators. Each Party is entitled to nominate one arbitrator. If. within one month after receipt of the request for arbitration filed by one Party, the other has not yet appointed an arbitrator, such arbitrator shall be appointed by the International Court of Arbitration of the International Chamber of Commerce on request of the first Party. The two arbitrators shall nominate the president of the court of arbitration, who shall be a lawyer qualified to practice and currently practicing as an attorney-at-law or as a judge. If they cannot come to terms within one month, the president of the court of arbitration shall be nominated by the International Court of Arbitration of the International Chamber of Commerce, on request of the more diligent Party.

15.4 If one of the arbitrators is unable to fulfil his/her duties for any reason the Party having nominated him/her shall nominate another arbitrator within one month, otherwise this arbitrator will be nominated by the International Court of Arbitration of the International Chamber of Commerce.

15.5 If the arbitrators or the president have to be replaced, the proceedings do not have to he started anew and will continue at the point where they were stopped.

15.6 The court of arbitration is hereby expressly instructed to act with most diligence and to keep any term as short as possible and to render the decision as soon as possible.

15.7 The Parties hereby stipulate that any arbitration hereunder shall be subject to the following rules: (a) the arbitrators may not award or assess punitive damages against either Party; and (b) each Party shall bear its own costs and expenses of the arbitration and one-half (1/2) of the fees and costs of the arbitrators, subject to the power of the arbitrators, in their sole discretion, to award all such reasonable costs, expenses and fees to the prevailing Party.

15.8 The Parties agree that the arbitrator's award shall be the sole and exclusive remedy between them regarding any claims, counter-claims, issues or accountings presented or pled to the arbitrator and that any costs, fees or taxes incident to enforcing the award shall be, to the maximum extent permitted by law, charged against the Party resisting such enforcement.

15.9 Notwithstanding the foregoing, any Party may bring a case of action against the other Party before any court of competent jurisdiction at the domicile of the defendant Party, if and to extent that any arbitral award rendered in the arbitration proceedings is unenforceable.

15.10 Subject to the provisions of Article 15.9, in the event that an award is rendered pursuant to this Article 15 by an arbitrator in favor of HBP, the Parties

acknowledge and agree that such award shall be enforceable by HBP, and MGI hereby consents to the exclusive jurisdiction for purposes of enforcement of any such award against MGI to the United States District Court for the District of Delaware, or, if jurisdiction or venue cannot he laid therein, the jurisdiction of any courts in the State of Delaware. Each of the Parties hereby consents to the exclusive jurisdiction of such courts (and of the appropriate appellate courts) for the purposes set forth above.

ARTICLE 16 - ENTIRETY OF AGREEMENT AND SEVERABILITY

16.1 This Agreement supersedes all prior agreements and understandings, whether oral or written, made by either Party or between the Parties and constitutes the entire Agreement of the Parties with regard to the subject matter hereof. The Parties however acknowledge and understand that (a) the existence and validity of this Agreement depend upon and are conditional upon the existence and validity of the License Agreement and (b) in case of any discrepancy between the License Agreement and this Agreement, this Agreement shall be construed in a manner consistent with the License Agreement. This Agreement shall not be considered extended, cancelled or amended in any respect unless done so in writing and signed on behalf of the Parties hereto.

16.2 The Parties hereby expressly state that it is the intention of neither Party to violate any rule, law and regulations. If any provision of this Agreement is rendered invalid or unenforceable, the Parties agree to renegotiate such provision in good faith and to replace it with valid and enforceable provisions in such a way as to reflect as nearly as possible the intent and purpose of the original provision,

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate by their duly authorized officers.

For and on behalf of
HELSINN BIREX PHARMACEUTICALS Ltd

/s/ Riccardo Braglia
Riccardo Braglia
Proxy

/s/ Enrico Braglia
Enrico Braglia
Proxy

For and on behalf of
MGI PHARMA, INC.

/s/ Charles N. Blitzer
Charles N. Blitzer
President and Chief
Executive Officer

/s/ Leon O. Moulder, Jr.
Leon O. Moulder, Jr.
Executive Vice President

FIRST APPENDIX

To an Agreement between HELSINN BIREX PHARMACEUTICALS LTD and MGI PHARMA, INC. dated April 6th, 2001

THE PRODUCTS

Qualitative description of the Products as submitted to the United States Food and Drug Administration under IND 39,797 Amendment # 64 and to the Therapeutic Products Programme in Canada under IND 9427-H0836-2IC

1. Palonosetron HCl Intravenous injection is supplied as a sterile, isotonic solution in 5 ml Type I clear glass vials each containing 5 ml of product. The product is clear and colorless solution, and contains the equivalent of either 0.05 mg/mL or 0.15 mg/mL of Palonosetron free base. The formulation also contains mannitol as a tonicifying agent, edetate disodium as a chelating agent and citrate buffer to maintain the pH of the solution at the target pH of 5 (±0.5).

2. The product is terminally sterilized.

SECOND APPENDIX

To an Agreement between HELSINN BIREX PHARMACEUTICALS LTD and MGI PHARMA, INC. dated April 6th, 2001

PRICE OF PRODUCTS

1. The Products will be supplied to MGI in finished packed form ready for marketing at a price corresponding to 29% (twenty-nine percent) of the Net Sale Price of said Products, provided however that, irrespective of the Net Sale Price of the Products, in no event said supply price for Products destined to the market of the United States of America shall be lower than USD $28.50 (United States Dollars twenty-eight and fifty cents) per vial in final package. An appropriate minimum supply price for Products destined to the market of Canada shall be discussed and established in good faith by the Parties in due time.

2. Within 31st May and 30th November in each calendar year throughout the term of this Agreement, MGI shall notify in writing HBP the Net Sale Price on which basis HBP shall calculate the supply price of the Products for the following six-month periods starting.

respectively, on 1st January and 15th July. Within 5 (five) days of the end of each Accounting Period, it shall be calculated the compensation for the supply of the Products so that it corresponds to 29% (twenty nine percent) of the Net Sales of said Accounting Period, provided however that sales by MGI of the 10% (ten percent) free goods which will he supplied in the First and in the second year from launch and of the 5% (five percent) free goods which will be supplied in the third year from launch in accordance with paragraph 3 hereunder, shall not be considered in the determination of Net Sales for the purpose of calculating the 29% compensation for the supply of Products. Resulting balances, if any, due to differences between the compensations to HBP calculated as above and the sum actually paid by MGI for the purchase of the Products, shall be liquidated between the Parties within 30 (thirty) days of the end of each calendar year.

3. The Parties further agree that HBP shall supply 10% (ten percent) free goods on top of the ordered quantities in the first and in the second year from launch, and 5% (five percent) free goods on top of the ordered quantities in the third year from launch.

HELSINN

April 10 2001

MGI PHARMA SIGNS EXCLUSIVE LICENSE AGREEMENT WITH HELSINN HEALTHCARE SA, FOR. PALONOSETRON, A PHASE 3 ANTI-EMETIC

MINNEAPOLIS end LUGANO, SWITZERLAND, April 10, 2001 – MGI PHARMA INC., (Nasdaq: MOGN) and HELSINN HEALTHCARE SA, a privately owned pharmaceutical group with headquarters in Switzer-land, today announced that they have signed the definitive agreement granting MGI PHARMA exclu-sive North American license and distribution rights to palonosetron. The signing of the letter of intent for this agreement was previously announced in February. Palonosetron is a potent and selective 5-HT, antago-nist with an extended half-life, in Phase 3 develop-ment for the prevention of chemotherapy-induced nausea and vomiting (CINV), Completion of the Phase 3 trials could allow for NDA (New Drug Application) submission in the first half of 2002. When launched, palonosetron will compete in the $1 billion North American CINV market.

"We are looking forward to entering the supportive care segment of oncology, the successful completion of the Phase 3 program and approve process for palonosetron, and the opportunity to demonstrate the role that this novel agent can have in preventing chernotherapy-induced nausea and vomiting for can-cer patients," commented Chuck Blitzer, president and CEO of MGI PHARMA. "Palonosetron is another exciting addition to our growing oncology product portfolio, representing another welt-advanced product that can be commercialized in the near term."

"Palonoseiron is our first product entry into the United States, and we are pleased to be working with MGI PHARMA for the North American distribution of this innovative product in the supportive cure segment of oncology." commented Riccardo Braglia, managing director of HEISINN We know that MGI PHARMA's proven commercial organization, its experienced oncology sales force and its present and future commitment to palonosetron's role within the 5-HT, antagonist marketplace will ensure the success of our new partnership."

About Palonosetron

When launched as a marketed product, palonosetron will be one of four products competing in the $1 billion North American market for 5-HT, antagonists. The extended half-life of palonosetron as compared to the other agents and the results of Phase 2 trials assessing efficacy beyond 24 hours differentiates palonesetron from the three currently marketed 5-HT, antagonists indicated for ClNV.

CINV is estimated to occur in 85 percent of cancer patients undergoing chemotherapy and can result in delay or even discontinuation of treatment, and the advent of 5-11 1 antagonists has revolutionized the management of nausea and vomiting experienced by cancer patients undergoing chemotherapy.

Palonosetron has been tested in a randomized, double-blind dose ranging Phase 2 trial at multiple sites throughout the U.S. that evaluated its efficacy and safety when administered in a single intravenous dose for the prevention of nausea and vomiting in patients receiving highly emetogenic chemotherapy.

Over 1,000 patients have participated in Phase 1 and Phase 2 trials of palonosetron. Based on these results, HELSINN Initiated a Phase 3 clinical trial program that is intended to enroll more than 1,900 patients in several well-controlled, double-blind trials comparing palonosetron to currently available 5-HT, antagonists – at approximately 80 centers in North America and Europe. Based on the extended half-life of palonosetron and the results of the Phase 2 trial, its efficacy wit be assessed over Day 2 through Day 5 following treatment, in addition to the primary efficacy measure of complete response during the 24-hour period after the start of chemotherapy. The most frequent adverse events associated with palonosetron are similar to those seen with other 5-HT, antagonists and include headache and constipation.

Under the terms of the exclusive license agreement. MGI PHARMA will make $11 million in upfront payments, already including the initial $5 million made upon signature of the letter of intent, and will make additional payments based on the achievement of certain milestones through the approval of palonosetron in the U.S. HELSINN will continue to fund and conduct all development of palonosetron MGI PHARMA will also pay royalties and product supply fees based upon net sales. HELSINN will supply finished product ready for distribution, the active ingredient of which is manufactured at HELSINN'S new state-of-the-art facility (HELSINN ADVANCED SYNTHESIS SA) dedicated to the production of high-potency active ingredients.

About MGI PHARMA

MGI PHARMA, INC. is an oncology-focused pharmaceutical company that acquires, develops and commercializes proprietary products that meet

patient needs and build shareholder value. MGI focuses its sales efforts solely in the United States and collaborates with other pharmaceutical or biotechnology companies for its products in international markets. For more information about MGI, please visit the Company's web site at www.mgipharma.com

BEGIN PRIVACY ENHANCED MESSAGE

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CONFORMED SUBMISSION TYPE: 8-K

PUBLIC DOCUMENT COUNT: 9

CONFORMED PERIOD OF REPORT: 20010322

ITEM INFORMATION:

ITEM INFORMATION:

FILED AS or DATE: 20010425

FILER:

COMPANY DATA:

COMPANY CONFORMED NAME: MGI PHARMA INC

CENTRAL INDEX KEY: 0000702131

STANDARD INDUSTRIAL CLASSIFICATION: PHARMACEUTICAL PREPARATIONS

[2834]

IRS NUMBER: 411364647

STATE OF INCORPORATION: MN

FISCAL YEAR END: 1231

FILING VALUES:

FORM TYPE: 8-K

SEC ACT:

SEC FILE NUMBER: 000-10736

FILE NUMBER: 1610572

BUSINESS ADDRESS:

STREET 1: 6300 WEST OLD SHAKOPEE RD

STREET 2: SUITE 110

CITY: BLOOMINGTON

STATE: MN

ZIP: 55438

BUSINESS PHONE: 6129357335

MAIL ADDRESS:

STREET 1: OPUS CENTER

STREET 2: 9900 BREN ROAD EAST SUITE 300E

CITY: MINNEAPOLIS

STATE: MN

ZIP: 55343

FORMER COMPANY:

FORMER CONFORMED NAME: MOLECULAR GENETICS INC

DATE OF NAME CHANGE: 19900812

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 22, 2001

MGI PHARMA, INC.
(Exact name of registrant as specified in its charter)

Minnesota
(State or other jurisdiction of incorporation)

0-10736
(Comission File number)

41-1354647
(I.R.S. Employer identification No.)

6300 West old Shakopee Road, Suite 110,
Bloomington, MN 55438
(Address of principal executive offices)

Registrant's telephone number, including area code:
(957) 346-4200

Not Applicable
(Former name or former address, if changed since last report)

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ITEM 5. OTHER EVENTS

On April 6, 2001. MGI PHARMA, INC. (the "Company") announced that it had entered into definitive agreements with Helsinn Healthcare SA ("Helsinn"), pursuant to which Helsinn granted to the Company exclusive license and distribution rights to the product candidate palonosetron in the United States and its possessions and territories (Puerto Rico, United States Virgin Islands), and Canada and its provinces, possessions and territories. Under the terms of the license agreement. the company will make $11 million in initial payments, which amount includes an initial payment of $5 million made upon the execution of a letter of intent in October 2000, and will make additional payments to Helsinn based on the achievement of development milestones. The Company will also pay royalties to Helsinn based upon net sales. Under the terms of a related supply agreement, an affiliate of Helsinn will supply the company's requirements of finished product. The Company will pay the affiliate product supply fees based upon net sales. The term of each of the agreements is ten years from the launch of the commercialized product, unless earlier terminated by the parties.

The license agreement and the supply agreement are attached as Exhibits 99.1 and 99.2 to this report and are incorporated herein by reference. This

summary of the provisions of the agreements is not complete and is qualified in its entirety by reference to the agreements. The press release dated April 10, 2001 announcing the execution of definitive agreements is attached as Exhibit 99.5 to this report and is incorporated herein by reference.

On March 22, 2001, the Company announced in a press release that it had initiated a new Phase 2 clinical trial of the anti-cancer compound irofulven for patients with refractory or recurrent advanced epithelial ovarian cancer. The press release is Filed as Exhibit 99.3 to this report and is incorporated herein by reference.

On March 28, 2001, the Company announced in a press release that six presentations on irofulven's anti-tumor activity and mechanism of action were made at the American Association for Cancer Research meeting held on March 24-28, 2001. The press release is filed as exhibit 99.4 to this report and is incorporated herein by reference.

On April 12, 2001, the Company announced in a press release that it had initiated an additional Phase 2 clinical trial of irofulven using an intermittent dosing schedule to treat hormone-refractory prostate cancer patients. The press release is filed as Exhibit 99.6 to this report and is incorporated herein by reference.

On April 18, 2001, the Company reported its earnings for the first quarter of 2001 in a press release, which is filed as exhibit 99.7 to this report and is incorporated herein by reference.

On April 25, 2001, the Company announced in a press release that a parent for the "Inhibition of DNA Methyltransferase" was recently granted to

MethylGene Inc., the partner with whom the Company has an exclusive North American license, research and development agreement for inhibitors of DNA methyltransferase. The press release is filed as Exhibit 99.6 to this report and is incorporated herein by reference.

ITEM 7. FINANCIAL STATEMENTS AND EXHIBITS

(c) EXHIBITS.

*99.1 License Agreement, dated as of April 6, 2001, between Helsinn Healthcare SA and MGI PHARMA, INC.

*99.2 Supply and Purchase Agreement, dated as of April 6, 2001, between Helsinn Birex Pharmaceuticals Ltd. and MGI PHARMA, INC.

99.3 Press Release, dated March 22, 2001.

99.4 Press Release, dated March 28. 2001.

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99.5 Press Release. dated April 10, 2001.

99.6 Press Release, dated April 12, 2001.

99.7 press Release, dated April 18, 2001.

99.8 Press Release, dated April 25, 2001.

* Pursuant to Rule 24-b of the Securities Exchange Act of 1934, as amended, confidential portions of Exhibits 99.1 and 99.2 have been deleted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized,

April 25, 2001

MGI PHARMA INC.

By: /s/ William C. Brown
William C. Brown
Chief Financial officer

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Exhibit 99.1

License Agreement between HELSINN HEALTH CARE SA and MGI Pharma, INC. for PALNOSETRON

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THIS AGREEMENT (hereinafter called "Agreement") is effective as of this 6th day of April 2001 (hereinafter called "Effective Date") between HELSINN HEALTHCARE SA, a corporation organized and existing under the law of Switzerland and having its registered office at Via Pian Scairolo, 6912 Pazzallo, Switzerland (hereinafter called "HHC") of the one part, and MGI PHARMA, INC., a corporation organized and existing under the law of the state of Minnesota, United States of America and having its registered office at 6300 West Old Shakopee Road, Suite 110, Bloomington, MN 50418-2318, USA (hereinafter called "MGI"), of the other part.

RECITALS

a. HHC carries on business as a licensing company, product developer and pharmaceutical trader and. in particular for the purpose of this Agreement, has in-licensed from the companies Syntex (U.S.A.) Inc. and F. Hoffman-La Roche AG by means of a License Agreement dated June 23, 1996 (hereinafter, the "Syntex Agreement") world-wide exclusive rights to certain patents and know-how to make, have made, develop, register, market, distribute and sell, directly

or indirectly, the Compound (as hereinafter defined) and pharmaceutical preparations containing said compound as active pharmaceutical ingredient.

b. MGI carries on business as a pharmaceutical company and, in particular for the purpose of this Agreement, represents that it is a reputable pharmaceutical company, having a size and a position on the market adequate to effectively market, distribute and sell the Products (as hereinafter defined) and that it has the necessary sales force to successfully sell the Products in the Field throughout the Territory (as hereinafter defined).

c. Prior to entering into discussions with HHC, MGI possessed no technology and limited information of its one (including publicly available information) relating to the Compound and/or the Products. The Parties entered on 25th May 2000 into a Secrecy Agreement by means of which HHC disclosed to MGI confidential information and data relating to the Compound and Products.

d. The Parties entered on October 5th, 2000 into a Letter of Intent on which basis they have performed respective appropriate due diligence for the purpose of establishing their interest

and willingness to enter into this Agreement, and hereby confirm that (i) each has been provided with full and complete access to such information as they deemed necessary or appropriate to conduct the diligence, and (ii) such due diligence has been completed to their full satisfaction.

e. MGI now wishes to acquire the right to act as HHC's licensee and distributor for the products in the Territory and HHC is willing to so appoint MGI under the terms and conditions hereinafter set forth.

f. The Parties agree that this preamble constitutes an integral part of this Agreement and all capitalized terms used in this preamble shall have the meaning as defined in Article 1 hereafter.

NOW, THEREFORE, in Consideration of the foregoing and of the mutual covenants and conditions herein contained, the Parties hereby agree as follows:

ARTICLE 1 - DEFINITIONS

The following terms as used in this Agreement have, unless the content clearly indicates otherwise, the following meanings:

1.1 "Accounting Period" means the quarters ending 31st March, 30th June, 30th September and 31st December in each year throughout the term of this Agreement.

1.2 "Affiliate" means an organization that, whether now or in the future, controls, is controlled by or is under common control with a Party. For the purposes of this definition, the terms "controls," "controlled by," and "under common control with" as used with respect to any Party, means the possession (directly or indirectly) of fifty percent or more of the voting stock or other equity interest of a subject entity with the power to vote, or the power in fact to control the management decisions at such entity through the ownership of securities or by contract or otherwise.

1.3 "Compound" means the active pharmaceutical ingredient (3as-2-[(S)-1-Azabicyclo[2.2.2]oct-3-yl]-2,3,3a,4,5,6-hexahydro-1-oxo-1H-benz[de]isoquinoline

hydrochloride, having the generic name palonosetron hydrochloride (INN) for use in human medicine.

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1.4 "FDA" means the U.S. Food and Drug Administration or any successor agency.

1.5 "Field" means the prevention of chemotherapy induced nausea and vomiting (CINV) in terms of the Regulatory Authorities approved indication.

1.6 "HHC's Other Distributors" means any distributor and/or licensee appointed by HHC to promote and sell pharmaceutical preparations containing the compound in any country of the world outside the Territory and outside the Field in the Territory.

1.7 "Improvements" means all improvements, modifications or developments relating to the Field and/or to the Product forms subject of this Agreement, which might improve the quality or improve consumer acceptance and/or patient compliance of the products. For clarity, except to the extent MGI has exercised its right of first refusal under Article 2.6, "Improvements" shall not include dosage forms other than the intravenous ("I.V.") formulation as shall be described in the Registration and/or indications other than within the Field.

1.8 "Know-how" means valuable, secret and substantial information regarding the Products in the Field, including but not limited to documentation and information on file with the FDA or other Regulatory Authority in support of the Registration, which may be necessary, useful or advisable to enable MGI to promote, market and sell the Products in the field in the Territory, as far as controlled by or available to,

and not prohibited to be disclosed or licensed by, HHC, all as listed in the First Appendix hereto and as is or will be specified in the documentation which HHC has delivered or will deliver to MGI after execution of this Agreement.

1.9 "Net sales" means the gross sales in local currencies of all Products sold in the territory by MGI and/or its Affiliates, including any local Affiliate in Canada, for arm's lenghth sales to any non-Affiliated third party less those normal and customary deductions made under Generally Accepted Accounting Principles to arrive at Product sales.***

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

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1.10 "Parties" means HHC and MGI and "Party" means either of them as the content indicates.

1.11 "Patent" means (a) the patents and the parent applications licensed or assigned to HHC pursuant to the Syntex Agreement, as listed in the Second Appendix hereto; (b) all patents in the Territory issuing from said applications; (c) any additions, divisions, continuations, continuations-in-part, amendments, amalgamations, reissues and re-examinations of such applications or patents in the Territory; (d) any confirmation, importation and registration patents thereof in the Territory, and (e) any extensions and renewals of all such patents and patent applications in

the Territory in whatever legal form and by whatever legal title they are granted.

1.12 "Products" means the pharmaceutical preparations for human use in I.V. dosage form, containing the compound as an active ingredient in the formulation that will be described in the Registration and such other formulations for which MGI exercises its right of first refusal pursuant to Article 2.6. The Current formulation as submitted to the Food and Drug Administration of the United States of America in the IND 39,797 Amendment # 64 and to the Therapeutic Products Programme of Canada in the IND 9427-H0836-21C is described in the Third Appendix hereto.

1.13 "Registration" means any official approval, or authorization by the Competent Regulatory Authority of each country in the Territory, which is legally required to lawfully market the Products in the Territory, including, without limitation, any governmental price approval or reimbursement approved under a national health insurance system.

1.14 "Regulatory Authority" means, with regard to the United States of America the United States Food and Drug Administration (FDA) and, with regard to Canada the Therapeutic Products Programme, or any other agency which shall be responsible for the issuance of the Registration throughout the term of this Agreement.

1.15 "Territory" means the United States of America and its possessions and territories (Puerto Rico, United States Virgin Islands), and Canada and its provinces, possessions and territories.

1.16 "Trademark" means the trademark DEDYS(R) or ONICIT(R), which are and shall be HHC's property, or under another trademark to be selected by the Parties, it being understood that HHC shall bear reasonable documented expenses in connection with such selection, and which shall be HHC's property.

ARTICLE 2 - GRANT OF RIGHTS AND COMPETITION

2.1 Subject to all terms and conditions of this Agreement, HHC hereby grants MGI, and MGI hereby accepts, an exclusive non-transferable and non-assignable (except as provided at Article 2.8 here below with regard to distribution, promotion and sale of the Products in the Field by a local Affiliate of MGI in Canada), royalty-bearing license under the Patents and to use the Know-how, to distribute, promote, market and sell the Products in the Territory for the Field.

Moreover, subject to all terms and conditions of this Agreement, HHC hereby grants MGI, which hereby accepts, an exclusive, non-transferable and non-assignable (except as provided at Article 2.8 here below with regard to distribution, promotion and sale of the Products in the Field by a local Affiliate of MGI in Canada). royalty-bearing license to affix the Trademark to the Products and to use it in connection with the distribution. promotion, marketing and sale of the products in the territory for the Field.

2.2 The exclusivity granted pursuant to this Article 2 means that only MGI may be licensed by HHC to distribute, promote, market and sell the Products in the Territory for the Field.

***

2.3 MGI agrees not to knowingly market, ship, distribute, promote, sell or otherwise put into circulation the Products outside the Territory and/or outside the Field and to expressly and consistently inform distributors and/or wholesalers for the products, by warning letters or

***Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

other appropriate and effective means, that the distribution and sale of the Products outside the Territory and/or outside the Field is prohibited and to enforce such prohibition as and when necessary. In the event that MGI enters into any agreements with its distributors and/or wholesalers for the Products, it shall use commercially reasonable efforts to include in any and all said agreements appropriate provisions prohibiting, to the maximum extent permissible under applicable laws and regulations, that the Products are distributed outside the Territory and/or outside the Field, and to enforce such provisions as and when necessary. Moreover, MGI undertakes to pass on to HHC any request for the Products coming to MGI from any party or for sale outside the Territory.

2.4 ***

2.5 MGI acknowledges and agrees that it shall not have the right to manufacture directly or indirectly, the compound and/or the Products. In order to maintain at all times the highest quality for the

Products and to ensure a scientifically proper and safe exploitation of the licensed Know-how and Patents and in order to maintain and to protect the goodwill of the Trademark MGI undertakes to purchase all of its Products' requirements exclusively from a source indicated or approved by HHC; provided that such source meets all requirements of applicable Regulatory Authorities and specifications for the Products applicable in the Territory.

2.6 The Parties hereby acknowledge and agree that the development and marketing of an oral formulation or the Compound will be useful for enlarging The market f pharmaceutical preparations containing the compound in the Field and undertake to discuss in good faith on the timing, costs and any other conditions relevant to the development, registration and marketing of such oral formulation. In addition. HHC shall offer to MGI a first negotiation right for the Territory (or some portion thereof) to distribute, promote, market and sell any new dosage form(s) and/or formulation(s) (other than the I.V. formulation as shall be described in the Registration) of the Products in the field (i) becoming available to HHC throughout the term of this Agreement and which HHC is free to offer in the Territory (or a portion thereof) or (ii) which development nod marketing pay be deemed of interest for the Parties or any of them.***

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange commission pursuant to rule 24b-2 of the Securities Exchange Act of 1934.

2.7 MGI acknowledges that there are or there may be different uses or indications of the Products and that the rights and licenses hereby granted by HHC are limited to the Field. HHC retains the right to, and shall be free to exploit at its own discretion into and outside the Territory, any and all uses or indications of the Products outside the Field, in whichever dosage form and/or formulation HHC may deem fit, including but not limited to I.V., and MGI shall have no rights in any respect whatsoever to such uses and/or indications outside the Field, provided that HHC shall not be entitled to use the Trademark or trademarks which are confusingly similar to the Trademark in respect of marketing and sale in the Territory of said uses and/or indications of the Products outside the Field; provided that such exploitation does not conflict with, or otherwise violate the terms and conditions of this Agreement.

2.8 MGI shall not have the right to sublicense or otherwise transfer any of its rights and/or obligations hereunder; provided that MGI shall be entitled to engage co-promotion partners in the United States, subject to HHC's prior approval, not to be unreasonably withheld. Moreover, MGI shall not have the right to sub-contract any of its rights and/or obligations hereunder, provided however that MGI shall be entitled to have the logistics and warehousing activities (excluding however invoicing and billing to customers) relevant to the Products carried out by its Affiliates or by third parties in the Territory. It is understood

that MGI shall have the right to have the Products distributed, promoted and sold in Canada by its local Affiliate whose name and address, and any change thereof, shall be timely notified to HHC.

MGI undertakes and warrants that its Affiliate in Canada shall strictly comply with MGI's applicable obligations and warranties stated in this Agreement and any breach of such obligations and/or warranties by such Affiliate shall be regarded in all respects and in particular for the purposes of Articles 11 and 17 hereunder, as a breach by MGI. Correspondingly, MGI shall be fully responsible towards HHC for any action and/or omission of its said Affiliate, and shall defend, indemnify and keep HHC wholly free and harmless from any connected claims, damages, liabilities, losses, costs and/or expenses. Moreover, MGI expressly undertakes and warrants that any agreement with respect to the Products between itself and its Affiliate in Canada shall be fully consistent with this Agreement and undertakes to send to HHC, upon HHC'S written request, a copy of any said executed agreement (with economic terms redacted) for the purpose of enabling HHC to verify compliance with terms and conditions hereof.

MGI shall be permitted to disclose to its Affiliate in Canada such Know-how and other relevant information to the extent strictly necessary and appropriate to correctly carry out its obligations hereunder, provided however than any such disclosure shall be made only under a confidentiality agreement, for the benefit of and approved in writing by HHC, having terms at least as restrictive as those provided herein.

2.9 MGI shall not enter into any agreement with third parties with respect to the Compound and/or the

Products, except as may be necessary for the purpose of a full and correct exploitation of the Products in accordance with all terms and conditions of this Agreement. upon HHC's written request, MGI shall send to HHC a copy of any said executed agreement (with economic terms redacted) for the purpose of enabling HHC to verify compliance with terms and conditions hereof. Nothing in this Agreement shall be construed as giving MGI any right to use or otherwise deal with the Know-how, the Patents and/or any other information received hereunder for purposes other than those of distributing, promoting, marketing and selling the Products in the Territory for the Field in accordance with the terms and conditions of this Agreement. In particular, and without limiting the generality of the foregoing, MGI hereby undertakes not to file any application for the Registration of generics of the Products in the territory or outside the Territory throughout the term of this Agreement.

2.10 MGI shall promptly inform HHC of any misappropriation, or threatened or presumed misappropriation of the Know-how which comes to its attention. HHC will decide on the steps to be taken after having discussed the case with MGI and MGI shall assist, bearing

exclusively its own internal costs and HHC bearing MGI's reasonable out-of-pocket costs, HHC in taking legal action, if deemed necessary by HHC, against such misappropriation.

2.11 Each Party shall promptly and fully inform the other if it has a reasonable basis to believe that there have been unauthorized sales of the Products into or

outside the Territory, and shall use practical efforts with all such persons to act consistently with the terms and conditions of this Agreement.

2.12 In the event that MGI fails to respect the limitations of the licenses granted under this Article 2 and MGI or its Canadian Affiliate knowingly distributes Products outside the Territory and/or outside the Field. or fails to enforce appropriate prohibitions on such distribution of Products outside the Territory and/or outside the Field by its distributers and/or wholesalers in accordance with Article 2.3 here above, MGI shall be deemed to be in material default, and HHC shall have the right, in its sole discretion, to terminate this Agreement by written notice to MGI, which breach is not cured within a sixty (60) days notice period.

ARTICLE 3 - EXCHANGE OF INFORMATION AND IMPROVEMENTS

3.1 Throughout the term of this Agreement, HHC shall supply MGI in writing and free of charge with any relevant Know-how, in addition to that already supplied at the Effective Date hereof, which may be or become available to HHC and which HHC is free to disclose. Notwithstanding the foregoing, nothing in this Agreement shall require HHC to obtain additional Know-how from third parties.

In the event that MGI should require technical assistance in connection with its initial sale of the Products in the Territory, HHC will use its commercially reasonable efforts to assist MGI for reasonable periods of time and at times convenient to HHC.

3.2 MGI shall supply HHC in writing or by any other appropriate support, free of charge, with any and

all technical and/or scientific information and data relating to the Products and/or the Compound, as soon as they are or become available to MGI throughout the term of this Agreement. MGI shall communicate any such information and data to HHC and MGI shall use such information and data for the purpose of the distribution, promotion and sale of the Products in the Territory for the Field in accordance with the terms and conditions of this Agreement. HHC shall have the right to use such information and data for the purpose of its business and to disclose the same to HHC's Affiliates and to HHC's other Distributors, which in turn shall have the right to use them for the purpose of the distribution, promotion

and sale or pharmaceutical preparations containing the compound outside the Territory and outside the Field in the Territory.

3.3 MGI's rights hereunder shall include any Improvement carried out by or which may be discovered, developed, invented or acquired by HHC, for use in accordance with the terms and conditions of this Agreement. Any Improvement which may be carried out by or which may be discovered, developed, invented or acquired by MGI, its officers, agents or employees, may be used by MGI for the purpose of the distribution, promotion and sale of the Products in the territory for the Field in accordance with the terms and conditions of this Agreement and will be promptly disclosed and is hereby automatically licensed free of charge to HHC on an exclusive basis even as to MGI (except for those MGI'S activities described here above) and HHC shall have the right to sublicense the

above Improvements to HHC's Affiliates and to HHC's Other Distributors for use outside the Territory and outside the Field in the Territory MGI shall not incur any obligation to any third party which may prohibit or impair its ability to disclose and license Improvements to HHC.

3.4 All Know-how, Improvements and/or other information and data disclosed to MGI hereunder are at all times and shall after expiration or termination of this Agreement for any reason remain HHC'S sole and exclusive property.

ARTICLE 4 - DEVELOPMEHT AND REGISTRATION OF PRODUCTS

4.1 MGI hereby acknowledges and agrees that

4.1.1 at the Effective Date of this Agreement the Products are under development by HHC for the purpose of submitting the relevant Registration application to the Regulatory Authorities of the Territory,

4.1.2 the development of the Products by HHC may be interrupted or discontinued by HHC as set forth in Article 4.2, if said development becomes commercially unreasonable, or the relevant results may be negative or unfavorable,

4.1.3 the development mark presently carried out will not necessarily result in the grant of the Registration of the Products and

4.1.4 HHC makes no warranty and nothing in this Agreement may Or shall be construed as a warranty by HHC that the Products obtain the Registration or that a

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Product can be developed and registered from the know-how and MGI shall have no claim against HHC arising out of any delay or refusal by the Regulatory Authorities to issue the Registration in any way whatsoever.

4.2 HHC will use commercially reasonable efforts to complete the development of the Products in accordance with the Development Chart attached as Fourth Appendix hereto and, subject to satisfactory development of the Products and provided that no unforeseeable events occur or additional requests are made by the Regulatory Authorities with respect to the development of the Products described in the Development Chart hereto attached, to file the NDA for the Products in the United States of America not later than ***. ***

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the securities Exchange Act of 1934.

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4.3 Applications for the Registration in the Territory shall be filed by HHC in its own name and at its own expenses, HHC shall also pay all administrative fees for the maintenance in force of the Registration throughout the term of this Agreement.

4.4 MGI expressly acknowledges and agrees that HHC is and shall at all times remain the sole and exclusive owner of the Registrations and that ownership of said Registrations and any and all rights,

title and interest (including any accompanying goodwill) are, and shall at all times remain, vested in HHC.

4.5 After approval of the NDA for the Products in the United States and compliance by MGI with the provision of Article 7.1.5 hereunder, MGI shall be appointed by HHC as HHC's agent with respect to the NDA for the Products in the Field ("FDA Agent") and shall manage and carry out on behalf of the HHC all relevant communications and relations with the FDA. In addition, MGI shall be entitled to participate in all negotiations and discussions between HHC and the FDA regarding any labeling for the Products in the Field with the exception of those activities specifically listed in the Fifth Appendix hereto, which shall be performed and carried out by HHC. Nothing in this Agreement precludes HHC from appointing an FDA Agent on different NDAs for products other than the Products (including, without limitation, any new dosage form(s) and/or formulation(s) of the Products in the Field under the terms provided at Article 2.6 hereabove) or for the Products outside the Field or from changing HHC's corporate agent in the United States ("U.S. Agent") at any time.

All said activities, communications and relations as well as MGI's role of HHC's FDA Agent as described above shall be performed by MGI in close coordination with HHC, directly or through third parties, as the holder of the Registrations. In particular, MGI shall copy within 48 hours and keep HHC fully and promptly informed, throughout the term of this Agreement, of all communications received from the Regulatory Authorities of the Territory concerning the Products and/or the Compound. Without prejudice to full compliance by both Parties with any obligations

established by applicable laws and regulations of the Territory with regard to adverse events reporting and any other deadlines set by Regulatory Authorities, any and all communications to Regulatory Authorities relevant to the Compound and/or the Products and connected with the activities described above, shall be sent by MGI only after the relevant contents have been described above, shall be sent by MGI only after the relevant contents have been discussed with and approved in writing by HHC, which approval shall be deemed to have been given if HHC does not otherwise respond within ten working days in Switzerland of receipt of such proposed communication; provided however, that MGI shall not be required to obtain such prior approval with respect to those mutually agreed routine administrative communications

with the FDA. MGI further undertakes and warrants that it shall at all times strictly comply with any and all laws, rules and regulatory requirements in force in the Territory in connection with the activities, communications and relations contemplated herein.

4.6 MGI shall store and distribute, and shall cause the Products to be stored and distributed according to applicable current Good Manufacturing Practice or any other applicable laws and regulations. MGI shall permit HHC's representatives, during normal business hours and upon three business days advance notice in writing, to inspect those areas of the warehouses of MGI, its Affiliates and distributors where the Products are stored, for the purpose of verifying compliance with applicable laws and regulations as well as with this Agreement.

4.7 If material alterations, modifications or amendments of this Agreement or of the Products are imposed by any Regulatory Authority as prerequisites for the grant or the continuation of the Registration of any of the Products, or if Registration of any of the Products is suspended or withdrawn by any said Regulatory Authority, each Party shall notify the other promptly after receipt of notification from such Regulatory Authority and the Parties shall endeavor to agree upon a reasonable and mutually acceptable resolution thereof. In the event that the Parties are unable to agree upon such a resolution. HHC shall have the right at its sole discretion, upon written notice to MGI, to delete the Product or products in question from this Agreement or to take any other measure which it reasonably deems necessary or advisable and, if necessary, to terminate this Agreement, in which case the consequences provided for at Article 17.6, 17.7 and 17.8 hereunder shall apply, it being understood that in any case, except as expressly provided in Article 11 of, this Agreement, HHC shall have no obligation, liability or responsibility whatsoever to compensate, indemnify or reimburse MGI for any payments, damages, losses, costs or expenses incurred by MGI in connection with this Agreement or termination hereof and that the payments already effected by MGI at the effective date of termination pursuant to Article 7 hereunder shall be retained by HHC.

4.8 MGI shall collaborate with and assist HHC and/or any of HHC's Other Distributors for the purpose of obtaining Registrations outside the Territory and/or, outside the Field in the Territory. Such collaboration and assistance shall include, but not be limited to, doing all such acts as may be required by HHC for the purpose of permitting access

and maximum use by HHC and/or HHC's Other Distributors of the documentation and results of the activities described at Article 4.5 hereabove and of development work on the Products carried out by MGI pursuant to Article 5.3 here below. HHC shall reimburse MGI for reasonable out-of-pocket expenses incurred in providing such collaboration and access.

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4.9 Each Party undertakes to give the other Party full, accurate and prompt information in writing with regard to adverse events associated with the use of the Products, whether or not ascertained to be definitely attributable to the Products or the Compound, in strict accordance with the procedures and rules established in the Sixth Appendix attached to this Agreement.

4.10 In the event of a recall, complaint, field alert, product withdrawal relevant to the Products marketed by MGI in the Territory, the Parties shall strictly follow the procedures and rules established in the Seventh Appendix to VHS Agreement.

4.11 MGI shall permit HHC and/or any authorized representative or consultant of HHC to enter MGI's premises, as well as the premises of MGI's Affiliates and/or distributors in the Territory, during normal business hours and upon at least three (3) business days advance notice, to audit and verify compliance by MGI its Affiliates and distributors with regulatory and other requirements in force in the territory, as well as with this Agreement, with respect to all aspects related to Registration and to correct and safe distribution, promotion, marketing and sale of the Products in the Territory or in connection with any recall contemplated by Article 4.10 hereabove.

Such audit shall include, without limitation, the right to examine any interval procedures or records of MGI, its Affiliates and distributors relating to the Products. MGI shall give and shall cause its Affiliates and distributors to give, all necessary assistance for a full and correct carrying out of the audit by HHC. No such monitor and/or audit by HHC shall relieve MGI, its Affiliates and distributors of any of their obligations under this Agreement in any way whatsoever.

In the event that any Regulatory Authority or any other competent authority of the territory carries out or gives notice of its intention to carry out any inspection or audit of MGI, its Affiliates or distributors or otherwise takes any action in relation to the Products, MGI shall immediately notify HHC in full details and shall use commercially reasonable efforts to insure that HHC shall have the right to be present at and to participate in any such inspection or audit.

ARTICLE 5 - POST-REGISTRATION DEVELOPMENT

5.1 HHC shall use commercially reasonable efforts to provide any further clinical and product development that may be requested by any Regulatory Authority in the Territory for the maintenance of the Registration.

5.2 MGI acknowledges that the performance of additional post-approval trials may be needed to market Products more effectively in the Territory.

5.3 MGI shall not undertake nor carry out any trial relevant to the Products without the prior written

approval of HHC. MGI shall perform and fund any trials mentioned at article 5.2 hereabove in accordance with a development plan to be agreed upon in advance with HHC. All relevant protocols shall have to be discussed and approved in writing by HHC. Any and all data, information and know-how whether patentable or not, arising from said trial will be promptly disclosed and is hereby automatically licensed free of charge to HHC on an exclusive basis even as to MGI (provided that MGI shall have the right to use such data, information and know-how solely for the purpose of the distribution, promotion and sale of the Products in the Territory for the Field in accordance with the terms and conditions of This Agreement) and HHC shall have the right to sublicense said data, information and know-how to HHC's affiliates and to HHC's Other Distributors for use outside the Territory and outside the Field in the Territory. MGI shall not incur any obligation to any third party which may prohibit or impair its ability to disclose and license said data, information and know-how to HHC. In addition, HHC shalt use commercially reasonable efforts to put at MGI's disposal for use in the distribution, promotion, marketing and sale of the Products in the Territory for the Field in accordance with the terms and conditions of this Agreement, any post-registration trial carried out by HHC's Other Distributors with regard to the Products.

ARTICLE 6 - TRADEMARK OF PRODUCTS

6.1 The Products shall be distributed, promoted, marketed and sold by MGI in the Territory exclusively under the Trademark.

6.2 MGI shall use the Trademark exclusively in connection with and for the purpose of the distribution promotion, marketing and sale of the Products for the

Field in the Territory. MGI acknowledges that it shall be entitled to no rights whatsoever in the Trademark except as is specifically granted pursuant to this agreement and then only to the extent of the express grant.

6.3 HHC shall register MGI, and MGI shall assist HHC in having MGI registered, as a licensee in the Trademark Register or the Territory as necessary and useful, in particular regarding the recordation as "Registered User" where corresponding legal provisions exist. Such registration shall be cancelled after expiration or termination of this Agreement for any reason upon the request of HHC.

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6.4 HHC's trade name and logo shall appear on all Products packaging, labels and inserts and other materials which MGI uses for the distribution, promotion, marketing and sale of the Products in such form and manner as shall be approved by HHC in writing in compliance with all requirements of applicable Regulatory Authorities.

6.5 MGI shall make no use of the Trademark except in the form and with the graphics authorized in advance by HHC. MGI shall for each use feature a prominent notice and acknowledgment of the registered Trademark ownership and license by HHC in conjunction with all usage of the Trademark. HHC shall have the right to review and approve all intended uses of the Trademark in any packaging, inserts, labels, promotional or other materials relating to the Products prior to actual use thereof.

6.6 MGI will not alter, obscure, remove, conceal or otherwise interfere with any markings, names, labels or other indications of the source of origin of the Products which may be placed by HHC on the Products.

6.7 MGI will not use nor apply for registration of any trademark, trade-name or logo in connection with the Products, nor shall it use or apply for registration of any trademark, logo or design which includes the Trademark, alone or in combination, in or outside the Territory, without the prior written authorization of HHC, which authorization HHC may withhold in its sole and absolute discretion.

6.8 Nothing contained in this Agreement shall be construed as giving MGI a right to use the Trademark or Portions thereof or any word confusingly similar to the Trademark or the name "Helsinn" as MGI'S corporate name or any part thereof. Throughout the term of this Agreement and thereafter, MGI shall not use nor apply for registration of, any mark, logo or design, in or outside the Territory, which is, or is likely to be, confusingly similar to, or could cause deception or mistake with respect to, the Trademark or to the name "Helsinn" on any pharmaceutical or chemical or healthcare product or service.

6.9 Nothing contained in this agreement shall be construed as giving MGI the right to use the Trademark outside the Territory or for any other product than the Products and HHC may use, or license others to use the Trademark in all jurisdictions outside the Territory.

6.10 The Trademark shall always be used together with the sign "R" or the sign "TM" or such other

customary symbol or legend which identifies correctly the status of the Trademark.

6.11 MGI recognizes the exclusive rights of HHC regarding the Trademark and acknowledges that it shall not acquire any rights in respect of the Trademark of HHC in relation to the

Products or of the goodwill associated therewith and that all such rights and goodwill are, and shall at all times remain, vested in HHC.

6.12 HHC shall keep in force the Trademark by paying the necessary fees throughout the term of this Agreement and by using all reasonable efforts to defend any action or proceeding for cancellation of the Trademark, bearing the whole cost thereof and MGI shall render any reasonable assistance in this respect.

6.13 MGI shall promptly notify HHC of any threatened or presumed significant counterfeits, copies, imitations, simulations of, or infringement upon, the Trademark or the name "Helsinn" or of any other act or unfair competition which comes to its attention. HHC will decide on the steps to be taken after having discussed the case with MGI and MGI shall glee its full co-operation therefor at HHC's expense, should it occur that HHC for any reason decides not to defend the Trademark, then MGI shall have the right to take appropriate action for defending the Trademark in its own name with the consent of HHC. In such case, MGI shall bear all the costs and shall be entitled to retain any compensation paid by third persons in this respect.

6.14 MGI acknowledges that HHC has no adequate remedy under this Agreement or at law in the event that MGI were to use the Trademark in a manner not authorized by this Agreement and that HHC would, in such circumstances, be entitled to specific performance, injunctive or other equitable relief, including interlocutory and preliminary injunctive relief.

6.15 MGI shall be entitled to mark the Products packaging, labels and inserts with the MGI name and logo, in a manner reasonably acceptable to HHC.

ARTICLE 7 - COMPENSATIONS BY MGI

7.1 As consideration for the right granted and information disclosed under this Agreement, in addition to the amount of USD5,000,000 (United States Dollars five million) which has been paid by MGI to HHC in accordance with the Letter of Intent mentioned at recital (d) here above. MGI shall pay to HHC, upon occurrence of the following events, the following milestone payments, which shall not be refundable nor creditable towards future royalties:

7.1.1 At signature of this Agreement, MGI shall pay to HHC USD6,000,000 (United States Dollars six million), of which up to 50% may, at MGI's option, be paid in freely tradable shares of MGI common stock as better specified at Article 7.7 hereunder;

7.1.2 Six months after execution of this Agreement, MGI shall pay to HHC USD ***;

7.1.3 At Type B pre-NDA meeting with the FDA, MGI shall pay to HHC USD ***;

7.1.4 At NDA filing in the United States of America, MGI shall pay to HHC USD *** of which up to 50% may at MGI's option, be paid in freely tradable shares of MGI common stock as better specified at Article 7.2 hereunder;

7.1.5 At NDA approval in the United States of America, MGI shall pay to HHC USD ***.

The above milestone payments shall be paid by MGI to HHC by wire transfer of immediately available funds to an account designated in writing by HHC; provided that the payments described at Articles 7.1.2 and 7.2.3 shall be paid pursuant to the terms of an Escrow Agreement among the Parties and U.S. Bank Trust Association in the Form attached as Appendix 8 hereto, dated as of the effective Date hereof. The milestone payments described at Articles 7.1.1, 7.1.2, 7.1.3, 7.1.4 and 7.1.5 shall be paid within 15 (fifteen) days of occurrence of the relevant event. Failure to pay any of the milestones on a timely basis shall entitle HHC to terminate this Agreement if MGI fails to cure such breach within a 15 (fifteen) days notice period.

7.2 MGI agrees to promptly inform HHC in writing as soon as it elects to effect part of the milestone payments under Articles 7.1.1 and 7.1.4 hereabove in freely tradable shares of MGI common stock. In this case, MGI shall issue to HHC such number of freely tradable shares of MGI common stock calculated by dividing the amount to be paid in MGI common stock by the average of the closing prices for such MGI common stock (as reported in The Wall Street Journal or, if not reported therein, in another mutually agreed upon authoritative source for the *** trading days before the date of payment of the related milestone payment (the "original Price"). MGI shall deliver the certificate representing such shares to HHC by

overnight courier within five (5) business days after such date of payment. Such shares shall be duly authorized, validly issued, fully paid and non-assessable and shall be free and clear of any and all liens, claims or other encumbrances. Notwithstanding anything contained herein to the contrary. MGI shall not be entitled to elect to satisfy its payment obligation under Articles 7.1.1 or 7.1.4, as the case may be, in freely tradable shares of MGI common stock, if, at the time that the payment becomes due pursuant to Article 7.1.1 or Article 7.1.4 above, as the case may be, the ***

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 246-2 f the Securities Exchange Act of 1934.

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common stock of MGI is not listed on The NASDAQ national market System ("NASDAG/NMS") in accordance with the NASDAQ/NMS requirements set for continued Listing - Standard 2. HHC acknowledges that any shares received from MGI in payment of its milestone payment obligations under Articles 7.1.1 or 7.1.4 of this Agreement will be "restricted securities" within the meaning of Rule 144 under the U.S. Securities Act of 1933, and that such shares will not be transferable in the U.S. markets unless and until such shares are either registered under the U.S. Securities Act of 1933 on an exemption from such registration requirement is available. MGI agrees that, unless a registration statement enabling such shares to be freely tradable by HHC upon receipt has

been filed by MGI and declared effective by the U.S. Securities and Exchange Commission and HHC has received reasonable assurances that MGI will maintain the effectiveness of such registration statement until HHC fully liquidates such shares in accordance with the restrictions contained in the last sentence of this Article 7.2, in each case prior to the date of delivery of such shares, then MGI shall not be entitled to elect to make part of the milestone payment under Articles 7.1.1 or 7.1.4 in shares of MGI common stock. MGI and HHC hereby acknowledge that, in connection with any such registration of shares of MGI common stock, MGI and HHC will use their reasonable best efforts to negotiate in good faith a registration rights agreement for such registration on terms reasonable and customary for such agreements. ***. Notwithstanding the filing and effectiveness of such registration statement, HHC agrees that, in connection with any sale of such MGI shares on the NASDAQ/NMS (or on any securities exchange or other public trading market on which MGI common stock is than traded), the number of shares of MGI common stock sold by HHC on any day will not exceed 10% (ten percent) of the average daily trading volume of MGI common stock in that market for the five trading day period ending two trading days prior to the date of such sale; provided, however, that (i) any shares sold by HHC in one or more block sales of at least 20,000 shares each which are effected through a market maker for MGI common stock shall not be counted for purposes of the foregoing volume

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 246-2 of the Securities Exchange Act of 1934.

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limitations, and (ii) such volume limitations shall however not apply to the extent that they require HHC a period longer than 90 (ninety) days from the first sale of MGI's shares by HHC to sell MGI's shares.

7.3 In addition to the above milestone payments, MGI shall pay running royalties as follows:

7.3.1 in consideration of the license granted hereunder on the Know-how, MGI shall pay to HHC or HHC's nominee a royalty of *** on all Net Sales throughout the term of this Agreement. It is expressly agreed that in case the Know-how becomes publicly known other than by action of HHC, the above royalty shall continue to be payable throughout the term of this Agreement, without prejudice to the payment to HHC of additional damages in case the Know-how becomes publicly known by the action of MGI.

7.3.2 In consideration of the license granted hereunder on the Patents, MGI shall pay to HHC or HHC'S nominee a royalty of *** on all Net Sales until expiration of all said Patents, on a country-by-country basis.

7.3.3 In consideration of the license granted hereunder on the Trademark, MGI shall pay to HHC a royalty of *** on all Net Sales throughout the term of this Agreement.

7.3.4 Royalties due by MGI pursuant to this Article shall accrue in United States Dollars (with regard to sales in the United States of America) and in Canadian Dollars (with regard to sales in Canada) and payments shall be made by wire transfer of immediately available funds to an account designated

in writing by HHC in United States Dollars (or in Canadian Dollars, as applicable) within 30 (thirty) days after the end of each Accounting Period, in respect of the Net Sales achieved in that Accounting Period, without prejudice to HHC's right to be paid in accordance with the provisions hereof as well as to any other remedy which may be available to HHC in accordance with this Agreement and/or applicable law, late payments shall bear interests at the prime rate applicable in Switzerland as of the date such payment was originally due.

7.3.5 For the purpose of computing the volume of the Net Sales, the Products shall be deemed to have been sold by MGI or its Affiliates as mentioned at Article 2.8 hereabove on the date of invoicing or on the date of delivering, whichever is first to

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occur, the same to the customer by MGI or its Affiliates, and no deduction shall be made for bad or doubtful debts arising in connection therewith.

7.3.6 ***

7.3.7 MGI will add value Added Tax (VAT) if any. as and where provided by law, to all the royalty accounts rendered and pay such VAT directly to the competent authorities under its own responsibility, or, where so provided by law, mark the royalty accounts

with the notice: "VAT Zero rated", staring the title of the exemption or exclusion.

7.3.8 If any official authorization shall be required to enable MGI to effect any payments of compensations due and payable hereunder, MGI shall use its best efforts to secure such authorization within the times stipulated in this Article, and in the event that by reason of such authorization not having been granted the payment is delayed beyond the times so stipulated. MGI shall so advise HHC and shall effect payment by any other lawful mans indicated by HHC; failing such indications, MGI shall effect payment within 15 (fifteen) days of such authorization being granted.

7.4 All payments to be made pursuant to this Agreement represent actual amounts that HHC is entitled to receive and shall not be subject to any deduction for any reason whatsoever. In the event that such payments become subject to duties, taxes or charges of whatever kind or nature (excluding taxes on HHC's income), such payments shall be increased to such an extent as to allow HHC to receive the net amounts due under this Agreement.

7.5 MGI shall in no case be entitled to off set or otherwise withhold any payment due to HHC hereunder in view of possible, justified or unjustified, claims against HHC.

7.6 If there exists a tax treaty to avoid double taxation between Switzerland and the Territory which reduces the standard rate of withholding tax. MGI shall assist HHC in obtaining the

the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1954.

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necessary exemption of the withholding tax according to such treaty. Upon submission by HHC of adequate exemption forms or equivalent, if required, MGI shall deduct only Such reduced withholding tax from its payments to HHC and shall submit to HHC the corresponding receipts so that HHC may collect these amounts from its own tax authorities as a tax credit.

ARTICLE 8 - MARKETING AND SALE OF PRODUCTS

8.1 MGI hereby undertakes that it will launch the Products in the Field onto the whole market of each country of the Territory as soon as possible and in any case no later than *** from respective Registration and availability of the necessary commercial supply, and that it shall promptly communicate in writing the relevant launching dates to HHC.

8.2 MGI shall be entitled to resell the Products to its customers in the Territory at such prices as it may determine subject to all applicable laws of the Territory. MGI shall keep HHC fully and timely informed on the price of the Products in the Territory and shall promptly notify any change thereof.

8.3 MGI hereby undertakes and warrants that it shall distribute, promote, market and sell the Products throughout the Territory under its corporate name and responsibility and at its own expense. MGI also undertakes and warrants that distribution, promotion, marketing and sale of the Products in the Territory shall fully comply with all laws, regulations

and requirements at any time being in force in the Territory and shall be fully consistent with the conditions and requirements of the Registration.

8.4 Marketing, advertising and promotional materials concerning the Products and training manuals for MGI's medical representatives shall be developed and prepared by MGI at its own expense and in coordination with HHC, which shall render reasonable assistance in this respect. HHC shall have the right to review and approve the final draft of any said material in advance of print thereof, for the purpose of ensuring compliance of said materials with the international profile and marketing strategy of the Product and the compound, provided that approval by HHC shall he deemed to have been given if HHC does not otherwise respond within ten working days in Switzerland of receipt of such materials.

8.5 MGI shall promote and distribute the Products in accordance with the Product profile and positioning reviewed with HHC end shall regularly supply HHC not later than September

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30 in each year throughout the term of this Agreement with its marketing and promotion plans which shall be discussed in good faith with HHC and shall have to be approved in writing by HHC, which approval shall not be unreasonably withheld or delayed. A marketing

strategy for the Products shall be developed and prepared by MGI consistent with the Registration and with the international profile of the Products as established by HHC. MGI shall keep HHC informed on all its promotional and marketing activities in the Territory regarding the Products and periodic meetings shall be organized between the Parties in order to discuss any and all aspects relevant to the promotion and marketing of the Products in The Territory.

8.6 MGI shall promptly supply HHC free of charge with on copies, in accordance with HHC's reasonable requests, of all marketing, advertising and promotional materials relevant to the Products and of the training manuals for its medical representatives and subject to Article 14.5, HHC shall be free to use, directly or indirectly, any such material for its business inside the Field outside the Territory. In no event shall HHC have the right to use such material in the Territory whether inside or outside the Field.

8.7 MGI undertakes to fully develop and pursue the market for the Product in the Field throughout the Territory. Throughout the term of this Agreement, MGI shall, at its own expense, maintain an active sales organization for marketing and selling the Products in the Field throughout the Territory, maintain an adequate and representative stock of the Products to meet market demand in the Territory and undertakes to effectively distribute, advertise, market, sell and promote the sale and use of the Products in the Field throughout the Territory. ***.

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the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

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8.8 MGI shall, within September 30th in each year throughout the term of this Agreement, provide HHC with an annual sales forecast in units for each of the Products. It is also agreed that MGI shall develop and supply HHC with sales forecast for 3 (three) years, starting from the date of Registration and revised annually.

8.9 MGI shall make clear in all dealings with its customers and prospective customers that it is acting as licensee and distributor of the Products and not as agent of HHC.

8.10 The final package of the Products, as well as any change thereof, shall be discussed in good faith and mutually agreed by the Parties and shall comply with all requirements of applicable Regulatory Authorities.

8.11 All packaging, insert, sheets labels, advertising and other materials relevant to the Products shall bear the notice "Distributed under license from Helsinn Healthcare SA, Switzerland in such form and manner as HHC may deem appropriate subject to any applicable regulatory requirements in the territory.

ARTICLE 9 - RECORDS AND REPORTS

9.1 MGI shall submit to MGI together with each royalty payment a written royalty statement signed by a responsible officer of MGI which shall show the units of Products sold or otherwise disposed of by MGI, the unit price, the gross sales and the Net Sales of each of the Products, its stock of Products, the quantity of

distributed free medical samples, a detailed listing and appropriate evidence and rationale of any and all discounts granted for each client, wholesaler and/or distributor and any other relevant information in sufficient detail to permit to HHC to determine and verify the royalties due to HHC. Throughout the term of this Agreement and for a period of at least 3 (three) years thereafter, MGI shall keep complete and accurate books, records and accounts in accordance with sound accounting practice covering all its operations hereunder as necessary to determine and verify the units of Products sold or otherwise disposed of by MGI, the gross sales and the Net Sales and the amount of royalties due to HHC. HHC shall have the right, at any time throughout the term of this Agreement and for a period of three years thereafter, during normal business hours and soon at least three (3) business days advance notice, to have such books, records and accounts inspected and audited by its duly authorized representatives or, at HHC'S discretion, by an independent certified public accountant to be nominated by HHC and reasonably acceptable to MGI. MGI shall fully co-operate with HHC, its authorized representatives or independent certified public accountant and make available all work

papers and other information reasonably requested in connection herewith. In the event the inspection or audit reveals that MGI's reports are not in accordance with actual sales and that an underpayment has occurred, MGI shall immediately pay to HHC any underpaid royalties within 10 (ten) days of the date HHC delivers to MGI the relevant inspection or audit report. In case of an underpayment of at least five

percent (5%) of the amounts owing during the audited period, MGI shall also bear all the costs of the inspection or audit and any overdue amounts hereunder shall bear interest at the prime rate applicable in Switzerland as of the date such payment was originally due.

9.2 Within 10 (ten) working days in the United States of America from the end of each month throughout the term of this Agreement, MGI shall supply HHC with a written report showing the units of Products sold and the units of free medical samples distributed during such month in the Territory.

9.3 MGI shall promptly provide HHC with written reports of any importation or sale of any pharmaceutical preparation containing the Compound in the Territory of which MGI has knowledge from any source other than HHC, as well as with any other Information which HHC may reasonably request in order to be updated on the market conditions in the Territory.

ARTICLE 10 - REPRESENTATIONS AND WARRANTIES

10.1 HHC hereby represents and warrants to MGI as follows:

10.1.1 HHC has been duly organized and is validly existing as a corporation in good standing under the laws of Switzerland. HHC has the corporate power and authority to enter into this Agreement and to consummate the transactions contemplated by this Agreement.

10.1.2 The execution delivery and performance of this Agreement, and the consummation of the transactions contemplated by this Agreement, by

HHC have been duly and validly authorized by all requisite corporate actions. This Agreement constitutes a legal, valid and binding agreement of HHC enforceable against HHC in accordance with its terms.

10.1.3 The execution, delivery and performance by HHC of this Agreement requires no action by or in respect of, or consent or approval of, or filing with, any Governmental Authority.

10.1.4 The execution. delivery and performance by HHC of the contemplated transactions do not and will net (A) contravene or conflict with the charter or bylaws f HHC. as applicable, (B) contravene or conflict with or constitute a violation of any provisions of any applicable law binding upon HHC, or (C) constitute a default in any material respect under or give rise so any right of termination, cancellation or acceleration of, or to a loss of any material benefit to which HHC is entitled.

10.1.5 There is no action, suit, investigation or proceeding pending against, or to the knowledge of HHC, threatened against or affecting, HHC before any court, arbitrator or any governmental authority, including but not limited to Regulatory authorities, that in any manner challenges or seeks to prevent, enjoin, alter or materially delay the contemplated transactions, and, to the knowledge of HHC, there is no reasonably valid basis for any such action, suit investigation or proceeding to be brought.

10.1.6 The persons executing this Agreement on behalf of HHC are duly authorized to do so and by so

doing have bound HHC to the terms and conditions of this Agreement.

10.1.7 HHC has received no notice from any of third party licensors that it is in material breach of any of its obligations under the Syntex Agreement, and it is not aware of any material breach of the Syntex Agreement. The Syntex Agreement constitutes a legal, valid and binding agreement of HHC, enforceable against HHC in accordance with its terms.

10.1.8 HHC has licensed sufficient rights to The Parents and Know-how order the Syntex Agreement and, other than the grant of license to third party manufacturers, HHC has not assigned and/or granted licenses to the Patents or Know-how in the Territory for the Field, or entered into any inconsistent prior obligations, to any other person or entity that would restrict or impair the rights granted hereunder to MGI.

10.1.9 To the actual knowledge of HHC, (i) as of the Effective Date hereof the Patents are valid and in full force and (ii) as of the Effective Date hereof it is not aware of any existing or pending patents of third parties which would be infringed by the marketing and sale of the Products in the Field in the territory in accordance with all terms and conditions of this Agreement.

10.1.10 None of the materials provided to MGI pursuant to its due diligence requests contained any untrue statement of material fact.

10.2 MGI hereby represents and warrants to HHC that:

10.2.1 MGI is a corporation duly incorporated, validly existing and good standing under the laws of the state of its incorporation and has all corporate powers and all governmental licenses, authorizations, consents and approvals required to carry on its business as low conducted and as contemplated to be conducted in connection with the transactions contemplated by this Agreement (the "contemplated Transactions"). MGI is duly qualified to do business as a foreign corporation in each jurisdiction where the character of the property owned or leased by it or the nature of its activities (after giving effect to the Contemplated Transactions) make such qualification necessary to carry on its business except where the failure to so qualify would not have a material adverse effect on MGI.

10.2.2 The execution, delivery and performance by MGI of this Agreement and the consummation by MGI of the Contemplated Transactions are within the corporate powers of MGI, and have been duly authorized by all necessary corporate action on the part of MGI. Each of this Agreement and the Escrow Agreement constitutes a legal, valid and binding agreement of MGI, enforceable against MGI in accordance with its terms.

10.2.3 The execution, delivery and performance by MGI of this Agreement requires no action by or in respect of, or consent or approval of. or filing with, any Governmental Authority. other than filings with the SEC in fulfillment of MGI's disclosure obligations under U.S. securities laws.

10.2.4 The execution, delivery and performance by MGI of the Contemplated transactions do not and will not (A) contravene or conflict with the charter or bylaws of MGI, as applicable, (B) contravene or conflict with or constitute a violation of any provisions of any Applicable Law binding upon MGI or (C) constitute a default in any material respect under or give rise to any right of termination, cancellation or acceleration of any agreement or instrument to which MGI is a party, or to a loss of any material benefit to which MGI is entitled.

10.2.5 There is no action, suit, investigation or proceeding pending against, or to the knowledge of MGI, threatened against or affecting, MGI before any court, arbitrator or any governmental authority, including but not limited to Regulatory Authorities, that in any manner challenges or seeks to prevent, enjoin, alter or materially delay

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the Contemplated Transactions, and, to the knowledge of MGI, there is no reasonably valid basis for any such action, suit investigation or proceeding to be brought.

10.2.6 As of February 28, 2001, the authorized capital stock of MGI consists of 30,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of February 28, 2001, (i) 15,538,545 shares of MGI's common stock are issued and outstanding, (ii) no shares of MGI's common stock are issued and held in the treasury of MGI and (iii) 4,075,749 shares of MGI's common stock are reserved for issuance upon exercise of options, warrants, convertible securities or any other right to acquire shares of common stock. There are no shares of preferred stock outstanding or

reserved for issuance upon exercise or conversion of options. The common stock to be issued to HHC in accordance with the terms of this Agreement, if, any, will be, when so issued, duly authorized, validly issued and outstanding and fully paid and non-assessable such shares of common stock shall be freely tradable by HHC and shall not be subject to any preemptive rights.

10.2.7 MGI has heretofore delivered to HHC MGI's Form 10-K for the year ended December 31, 2000 ("10-K") and each and every report filed with the United States Securities and Exchange Commission ("SEC") since the date thereof. As of its date, except for any information corrected or superseded by subsequent filings with the SEC, such reports did not contain any untrue statement of material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading. The audited consolidated financial statements of not and its subsidiaries, and the notes thereto included in the 10-K have been prepared in accordance with GAAP and present fairly the consolidated financial position of MGI and its subsidiaries as of the date thereof and the results of their consolidated operations and changes in consolidated financial position for the periods then ended. The unaudited consolidated financial statements included in MGI's 2000 quarterly reports filed on Form 10-Q ("10-Q") comply as to form in all material respects with the published rules and regulations of the SEC with respect thereto; and such unaudited financial statements are fairly presented in conformity with generally accepted accounting principles (except as permitted by form 10-Q) applied on a basis

substantially consistent with that of the audited financial

statements included in the 10-K. subject to normal year-end adjustments. Except as and to the extent reflected or reserved against in the balance sheet included in the 10-K or 10-Qs, in the notes thereto or as covered by valid and collectible insurance or other collectible claim for reimbursement, except as set forth in a schedule referred to in this Agreement or in a press release issued by MGI since the filing of the most recent 10-0, there has been no material adverse change in the business, properties on financial condition of MGI and its subsidiaries taken as a whole.

10.2.8 The persons executing this Agreement on behalf of MGI are duly authorized to do so and by so doing have bound MGI to the terms and conditions of this Agreement.

10.2.9 MGI understands and acknowledges that, as of the Effective Data hereof, there is no assurance that there is or will be a market for the Products, and MGI expressly assumes the risk that the Products will be commercially marketable. HHC shall have no liability to MGI of any kind, nor shall MGI be entitled to a return or a refund of any portion of the payments specified at Article 7 hereof if, for any reason, the Registration is not granted in any part or the whole of the Territory or a commercial market does not develop for the Product.

10.2.10 MGI has been given full and complete access to such information and records of HHC as it deemed appropriate to conduct due diligence and such

due diligence has been performed to she full satisfaction of MGI.

ARTICLE 11 - LIABILITIES, INDEMNITIES AND INSURANCE

11.1 MGI shall be fully liable for and shall defend, indemnify and hold HHC and its Affiliates, officers, directors and employees wholly free and harmless from and against any and all liabilities, damages, losses, costs, taxes, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgements or administrative and judicial orders arising out of or resulting from any claim, suit or proceeding to the extent arising out of or resulting from (a) the use of the Know-how, the Trademark and the Patent in the Territory by MGI (except to the extent provides in Article 11.2 below); (b) any failure by MGI, its local distributors or Affiliates to comply with any applicable laws, regulations and/or administrative decision regarding the Registration and/or the Products; (c) the performance by MGI of its obligations as HHC's FDA Agent and/or the management and performance by MGI of the post-registration activities connected with the NDA for the Products, as described at Article 4.5 above: (d) the

performance by MGI or its agents of the development work relevant to the products as described at Article 5.3 above; (e) any defect in the results of the development work carried out by or on behalf of MGI as provided at Article 5.3 above; (f) the storage, distribution, sampling, record-keeping, analysis, transfer or sale of the Products by MGI or its agents; (g) the

promotion, advertising and marketing of the Products by MGI or its Affiliates; (h) misuse of the Know-how received hereunder by MGI or its agents; (i) failure of any Products supplied hereunder to comply with the applicable approved specifications in the event that such non compliance (l) could have been detected by MGI carrying out visual inspection on the supplied Products with ordinary diligence or (7) results from any Products which has been altered, changed, packed or re-packed, processed or otherwise treated other than in strict accordance with HHC's instructions and specifications; or (i) any negligent or wrongful act or omission and/or any breach by MGI or by any of its local distributors and/or Affiliates of any of MGI's obligations, representations and/or warranties hereunder.

11.2 HHC shall be liable for and shall defend, indemnify and hold MGI and its Affiliates, officers, directors and employees free and harmless from and against any and all liabilities, damages, losses, costs, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands. suits, penalties, judgements or administrative and judicial orders, but in no event in excess of the sums already paid by MGI under Article 7 hereabove, arising out of or in any way resulting from any claim, suit or proceeding to the extent arising out of or resulting from (a) a claim that the use of the Know-how and the Patent infringes any intellectual property right of any third party (but only to the extent HHC is covered by Syntex in this regard pursuant to the applicable provisions of the Syntex Agreement); (b) any failure by HHC or its Affiliates to comply with any applicable laws, regulations and/or administrative decision regarding the Registration and/or the Products; (c) the performance by HHC or its agents of

any development activities relating to the Products, as described at Article 4.2 above; (d) any defect in the results of the development work carried out by or on behalf of HHC as provided at Article 4.2 above; (e) the storage, distribution, sampling, record-keeping, analysis, transfer or sale of the Products by MC or its agents; (f) the promotion, advertising and marketing of the Products by HHC or its Affiliates' (g) misuse of the Know-how by HHC or its Affiliates; or (h) any negligent or wrongful act or omission and/or breach by HHC or its Affiliates of any of its obligations and/or warranties hereunder.

11.3 Being understood that each of the Parties hereto shall take all reasonable steps to avoid or mitigate any loss,. damage or liability which might give rise to a claim under this Agreement, a Party seeking indemnification pursuant to this Article 11 (an "Indemnified Party") shall give prompt and full written notice to the Party from whom such

indemnification is sought (the "Indemnifying Party") of the assertion of any claim or the commencement of any action, suit or proceeding in respect of which indemnity is or may be sought hereunder, provided however that no failure to give such notice or co-operation shall relieve the indemnifying Party of any liability and/or obligation hereunder (except to the extent the Indemnifying Party has suffered actual prejudice thereby). The Indemnifying Party shall have the sole right to control the defense and settlement thereof. The Indemnified Party will give the Indemnifying Party such information with respect thereto as the Indemnifying Party may reasonably

request and will co-operate with the Indemnifying Party in the defense of said claim, suit or proceeding as the Indemnifying Party may reasonably request. The Indemnified Party shall not, except at its own cost, voluntarily make any payment or incur any expense with respect to any claim, suit or proceeding without the prior written consent of the Indemnifying Party.

In addition, the Indemnifying Party shall be subrogated to the rights of the Indemnified Party against any third party, and such Indemnified Party hereby assigns to the Indemnifying Party all claims, causes of action and other rights which the Indemnified Party may then have against any third party, including Affiliates and in the case of HHC, against any contract manufacturer of the Products, with respect to the claim, suit or proceeding which is the subject of the claim for indemnification hereunder, conversely, and without in any way limiting the obligation of either Party to indemnify the other Party as herein provided, to the extent that either Party shall fail to perform its indemnification obligations under this Article 11, such Party owing a duty or indemnification hereby assigns to the other Party all claims, cause of action and other rights which the Party Owing such duty may then have against any third party, including Affiliates and, in the case of HHC, against any contract manufacturer of the Products, with respect to the claim, suit or proceeding.

It is understood and agreed that the operation and application of this Article 11.3 are however subject to any right of Syntex (U.S.A.) Inc. under articles 8.3. 8.4 and 8.5 of the Syntex Agreement, which are hereby acknowledged and accepted by MGI.

11.4 MGI shall be solely responsible towards its customers for handling all matters concerning the Products subject to cooperation with HHC on any recall or other regulatory matters that may be injurious to HHC. MGI shall be responsible for any expired Products, whether stored by MGI and/or its local distributors or returned by wholesalers, pharmacists, doctors, hospitals to whom said Products have been sold. MGI shall indemnify, defend and hold HHC and its Affiliates, directors, officers and employees wholly free and harmless from and against any and all liabilities, damages, losses, costs, expenses (including reasonable

attorneys' fees and other expenses of litigation and arbitration) claims, demands, suits, penalties, judgements or administrative and judicial orders arising therefrom; except with respect to any recall or other regulatory action arising from any breach by HHC or its Affiliates of any warranty, representation or other material obligation contained in this Agreement or the negligence or willful misconduct of HHC or its Affiliates.

11.5 Each Party shall indemnify and hold the other Party wholly harmless from and against any and all liabilities, damages, losses, costs, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgements or administrative and judicial orders arising out of any behavior contrary or in excess to the provisions of Article 18.1 hereunder.

11.6 THE SOLE REPRESENTATIONS AND WARRANTIES THAT HHC MAKES WITH

RESPECT TO THE MATTER CONTEMPLATED BY THIS AGREEMENT ARE EXPRESSLY SET FORTH IN ARTICLE 10.1. WITHOUT LIMITIMG THE GENERALITY OF THE FOREGOING, HHC MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, OF MARKETABILITY, CAPACITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE KNOW-HOW, THE PATENTS AND/OR THE PRODUCTS. NO ORAL OR WRITTEN REPRESENTATION BY OR ON BEHALF OF HHC SHALL BE INTERPRETED TO CONTAIN ANY SUCH WARRANTY. NEITHER MGI NOR ANY OF ITS EMPLOYEES OR REPRESENTATIVES IS AUIHORISED TO GIVE ANY WARRANTIES OR MARC ANY REPRESENTATION ON BEHALF OF HHC.

11.7 THE SOLE REPRESENTATIONS AND WARRANTIES THAI' MGI MAKES WITH RESPECT TO THE MATTER CONTEMPLATED BY THIS AGREEMENT ARE EXPRESSLY SET FORTH IN ARTICLE 10.2 AND MGI HEREBY DISCLAIMS ALL OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED. NO ORAL OR WRITTEN REPRESENTATION BY OR ON BEHALF OF MGI SHALL BE INTERPRETED TO CONTAIN ANY SUCH WARRANTY. NEITHER HHC NOR ANY OF ITS EMPLOYEES OR REPRESENTATIVES IS AUTHORISED TO GIVE ANY WARRANTIES OR MAKE ANY REPRESENTATION ON BEHALE OF MGI.

11.8 NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, NEITHER OF THE PARTIES SHALL BE LIABLE TOWARDS THE OTHER FOR INDIRECT, SPECIAL, PUNITIVE,

EXEMPLARY, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION LOSS OF PROFITS OR

REVENUES, REGARDLESS OF WHETHER SUCH DAMAGES WERE FORESEEABLE OR NOT. THIS CLAUSE WILL HOWEVER NOT BE APPLICABLE IN CASE OF BREACH BY MGI OF THE LIMITATIONS OF GRANTS AND THE NON-COMPETITION OBLIGATIONS STATED AT ARTICLE 2 AND BREACH BY EITHER PARTY OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS STATED AT ARTICLE 14 OF THIS AGREEMENT.

11.9 Each Party agrees to procure and maintain in full force and effect during the term of this Agreement valid and collectible insurance policies in connection with its activities as contemplated herein. In particular, MGI at its own cost shall cause HHC and their respective employees, officers, directors and contractors to be added as additional named insured throughout the term of this Agreement on all policies of general commercial liability insurance and product liability insurance covering MGI, which coverage shall, when MGI either initiates clinical trials on the Products or begins marketing or distributing the Products for commercial sale or for promotional purposes, have limits of liability which are commercially reasonable in the Territory but shall be not less than *** per loss occurrence. Within 5 (five) days of the Effective Date and of each beginning of each policy period, MGI shall provide HHC with a certificate evidencing the coverage required hereby and the

amount thereof. Such coverage shall be with a reputable insurance company having at least an A.M. Best "A" rating and shall have to be maintained for not less than 6 (six) years following expiration or termination of this Agreement for any reason or if such coverage is of the "claims made" type, for ten years following expiration or termination of this Agreement for any reason.

ARTICLE 12 - THE PATENTS

12.1 MGI agrees that any Products distributed, promoted, marketed and sold by it will be marked with a notice of patent rights as necessary or desirable under applicable law to enable the Patent to be enforced to the maximum degree.

12.2 MGI shall cooperate with HHC as may be reasonably requested by HHC and at HHC's expense for the purpose of filing for and obtaining patent extensions and supplementary or complementary protection certificates, if available, of the Patents under the relevant applicable laws of each country of the Territory.

12.3 HHC hereby undertakes that it shall use commercially reasonable efforts to cause Syntex to comply with its obligations under the Syntex Agreement with regard to maintenance.

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

defense and enforcement of the Patents in the Territory. In the event that Syntex fails to maintain, defend and enforce such Patents, then HHC shall use commercially reasonable efforts do so, to the fullest extent permissible under the relevant provisions of the Syntex Agreement.

12.4 MGI shall promptly inform HHC in writing upon its becoming aware of any possible third party infringement of the Patents. HHC shall thereafter promptly report the case to Syntex in accordance with the relevant Provisions of the Syntex Agreement, for appropriate action by Syntex and/or HHC. MGI shall provide assistance, bearing exclusively its well costs, as may be reasonably requested by HHC.

12.5 MGI shall promptly inform HHC in writing upon its becoming aware of any notice or claim that the distribution, promotion, marketing and sale of the Product in the Territory for the Field in accordance with the terms and conditions of this Agreement infringe any third party's patent rights, or in the event of the commencement of any suit or action for infringement of any such third party's rights. HHC shall therefore promptly report the case to Syntex in accordance with the relevant provisions of the Syntex Agreement, for appropriate action. MGI shall not settle or compromise any such suit or action without the prior written consent of HHC and shall provide assistance, bearing exclusively its own internal costs, as may be reasonably requested by HHC.

12.6 MGI shall fully co-operate with HHC in connection with any action or proceeding relating to the validity of the Patent, including if required being joined as a necessary party to such action or proceeding at HHC's expense.

ARTICLE 13 - THE SYNTEX AGREEMENT

13.1 MGI acknowledges and understands that the rights granted to it by HHC in this Agreement derive from the Syntex Agreement and are subject to the terms thereof, a copy of which with economic terms redacted MGI has reviewed. The Parties hereby acknowledge and agree that in case of any discrepancy or conflict between this Agreement and the Syntex Agreement, this Agreement shall be construed in a manner consistent with the Syntex Agreement, except for those obligations of HHC towards Syntex which do not have a material impact on MGI's obligations hereunder.

13.2 During the term of this Agreement, HHC agrees to comply in all material respects with its obligations under the Syntex Agreement to the extent necessary to preserve its rights in the Territory thereunder, except to the extent that such compliance is dependent upon MGI.

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13.3 During the term of this Agreement, MCI agrees to act in compliance with the Syntex Agreement to the extent required by the Syntex Agreement, including without limitation any confidentiality restrictions contained therein.

13.4 MGI acknowledges and agrees that HHC has acquired certain rights in and to the Compound pursuant to the Syntex Agreement and that any and all rights that MGI is acquiring pursuant to this Agreement are subject to, in all cases, the Syntex Agreement. Further, MGI acknowledges that under certain circumstances, Syntex has the right to

terminate certain of HHC's rights under the Syntex Agreement. HHC shall promptly provide MGI with a copy of any notice of termination it may receive from Syntex under the Syntex Agreement and the Parties shall thereafter discuss in good faith appropriate steps to cure such termination event.

ARTICLE 14 - CONFIDENTIALITY

14.1 MGI shall treat as strictly confidential, and shall solely for the purpose of and in accordance with this Agreement, the Know-how, Improvements and/or any information and/or document received hereunder or in connection with the Contemplated Transaction not generally known to the trade, including but not limited to non-public information relating to the Patent as well as the results of the development work performed hereunder (all hereinafter referred to as the "Confidential Information"). MGI shall not make such confidential information available to arty third Party, including any of its Affiliates, except to competent government agencies to which it will be necessary to disclose such information, and in this case (a) strictly to the extent requested by said agencies and (b) only upon exercise of its best efforts to cause said agencies to maintain confidentiality thereof.

14.2 Such confidential information shall only be made available to such employees of MGI who are directly and necessarily involved in the authorized use of Confidential Information and who are subject to a secrecy obligation by contract, to the extent strictly necessary to perform their duties and obligations hereunder.

14.3 Notwithstanding expiration or termination of this Agreement for any reason, these confidentiality and non-use obligations shall continue until the

confidential information has become generally known to the public, provided however that nothing contained herein shall in any way restrict or impair the right of MGI to use, disclose or otherwise deal with information which MGI can demonstrate to HHC by clearly convincing documentation:

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14.3.1 is or hereafter becomes part of the public domain through no act or omission of MGI, its employees, Affiliates and/or local distributors, or

14.3.2 MGI was in lawful possession of prior to receipt of the confidential information from HHC, or

14.3.3 previously was, or at any time hereafter is, received in good faith by MGI from sources other than HHC and which did not originate, directly or indirectly, from syntax, or

14.3.4 at the time of disclosure, was known by MGI or an Affiliate or local distributor. or after disclosure has independently developed by MGI, an Affiliate or local distributor without use of the Confidential Information.

14.4 Prior to the publication or presentation of any information or data arising from the activities described at Article 5.3 above, MGI shall submit to HHC a summary of the proposed publication or presentation prior to the submission thereof for publication or presentation. The purposes for such prior submission arc: (i) to provide HHC with the opportunity to review and comment on the contents of the proposed publication or presentation, (ii) to identify any Confidential Information to be deleted from the proposed publication or presentation, and (iii)

to agree in good faith on the contents and timing of such proposed publication or presentation.

14.5 HHC shall keep strictly confidential, in the same way mutatis mutandis as provided here above for term in respect of confidential information, any MGI Confidential Information (as defined herein) received from MGI hereunder, except as otherwise specifically provided in this Agreement. As used herein. the term "Confidential Information" shall mean all information disclosed by MGI to HHC, relating to the markets, customers, suppliers, patents or patent applications, inventions, know-how, data or information, products, research and development, procedures, designs, formulas, business plans, financial projections, employees, consultants or any other similar aspects MGI's present or future business, whether such information is disclosed in written, oral, electronic, graphic or other format.

ARTICLE 15 - FORCE MAJEURE

15.1 If the performance of this Agreement is prevented or restricted by government action, war, fire, explosion, flood, strike, lockout, embargo, act of God, or any other similar cause

beyond the control of the defaulting Party, the Party so affected shall be released for the duration of the force majeure, or such other period agreed between the Parties as being reasonable in all circumstances, from its contractual obligations directly affected by the force majeure, provided that the Party concerned shall:

15.1.1 give prompt notice in writing to the other Party of the cause of force majeure;

15.1.2 use commercially reasonable efforts to avoid or remove such cause of non-performance;

15.1.3 continue the full performance of this Agreement as soon as such cause is removed.

15.2 The Parties shall take all reasonable steps to minimize the effects of force majeure on the performance of this Agreement and shall, if necessary, agree on appropriate measures to be taken. Should the force majeure continue for more than 6 (six) months, then the other Party shall have the right to terminate this Agreement forthwith.

15.3 Notwithstanding anything contained in this Article 15, obligations to pay money accruing prior to the force majeure event are never excused by force majeure.

ARTICLE 16 - TERM

16.1 This Agreement comes into force at the Effective Date hereof, unless terminated earlier pursuant to the provisions hereof and subject to the validity of the Syntex Agreement, it shall remain in force for a period of 10 (ten) years from the date of launching by MGI of the first of the Products and, unless either of the Parties gives notice of Termination to the other Party in writing 6 (six) months before the termination of the initial or of any extension period, it shall be automatically renewed for periods of 3 (three) years.

ARTICLE 17 - TERMINATION

17.1 Each of the Parties reserves the right to terminate this Agreement in case of any substantial or persistent breach of any of the terms and conditions of

this Agreement by the other Party, including, without limitation, as provided at Articles 2.12 and 7.5.6 above. The defaulting Party shall be given in writing a 60 (sixty)-day period, except as otherwise specifically provided, to fulfil its obligations hereunder and, if after such period it is still in breach of

the Agreement, the other Party shall have the right to terminate this Agreement by written notice to the defaulting Party. In addition, MGI hereby acknowledges and agrees that HHC shall be entitled to terminate this Agreement by written notice to MGI in case of termination of any agreement between MGI and any third party for the supply of Products to MGI as per Article 2.5 above due to a breach by MGI.

17.7 Either Party shall have the right to terminate this Agreement upon written notice to the other Party, if such Party shall become insolvent or shall make an assignment for the benefit of creditors or become involved in receivership, bankruptcy or other insolvency or debtor relief proceedings, or any similar proceedings or in proceedings, voluntary or forced, whereby the party involved is limited in the free and unrestrained exercise of its own judgement as to the carrying out of the terms of this Agreement. The Parties intend that upon HHC's termination of this Agreement pursuant to this Article 17.2, all rights granted hereunder to MGI shall be terminated and revert to HHC. The Parties acknowledge and agree that all rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Article 365(n) of the Bankruptcy Code, licenses of rights to "intellectual property" as defined

under Section 101(52) of the Bankruptcy Code, and that MGI, as a licensee hereunder, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code.

17.3 In case the ownership or control (as this term is defined at Article 1.2 here above) of MGI or of a legal entity directly or indirectly owning or controlling MGI changes (whether by merger, consolidation, reorganization, take over, change in the ownership of the share capital or otherwise), details of any such change in ownership or control shall be notified in writing by MGI to HHC as soon as possible and in any case no later than 5 (five) days of its occurrence. HHC shall then have the right to terminate this Agreement by giving MGI or the new entity owning or controlling MGI 30 (thirty) days advance notice in writing if (i) the entity owning or controlling MGI has in its portfolio a product competing with the Products (as defined at article 2.4 here above) and/or (ii) MGI's commitments and investments on the Products in terms of promotion and marketing efforts, sales force activities, sales performance etc. are not maintained by said new entity.

17.4 ***

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

17.5 HHC shall have the right to terminate this Agreement by written notice to MGI if MGI fails to

launch the Products as provided in Article 8 hereabove, or if MGI or any of its agents, employees, Affiliates or distributors breaches the confidentiality and/or non use obligations provided for in Article 14 hereabove. MGI shall have the right to terminate this Agreement by written notice to HHC if HHC or any of its agents, employees or Affiliates breaches the confidentiality and/or non use obligations provided for in Article 14.5 hereabove.

17.6 Without limiting the generality of the foregoing, termination or expiration of this Agreement for any reason shall not extinguish any existing claims either of the Parties may have for indemnification and shall not preclude either of the Parties from pursuing any claim for indemnification such Party otherwise may have to the extent that the circumstances giving rise to such claim arose prior to, on or after the date of termination or expiration.

17.7 Upon expiration or termination of this Agreement for any reason, MGI shall:

17.7.1 subject to Article 17.7.4 hereunder, promptly cease any use and/or exploitation of the Registration;

17.7.2 subject to article 17.7.4 hereunder, promptly cease any use of the Trademark and not hold itself out as a distributor of the Products;

17.7.3 subject to Article 17.7.4 hereunder, promptly terminate using the Know-how, the Improvements and the results of the development work carried out in accordance tenth Article 5.3 hereunder and return or deliver all such materials to HHC without retaining copies, notes, summaries or translations thereof;

17.7.4 promptly terminate distributing, promoting, marketing and selling the Products onto the market,

provided that it shall have a three-month period to sell its existing stock of Products, subject to payment of royalties hereunder. Any stuck remaining at the expiry of said three months period shall be destroyed by MGI at MGI's expenses, unless otherwise directed by HHC.

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17.8 Unless otherwise set forth herein, the Parties' remedies under this Agreement are intended to be cumulative and not mutually exclusive.

ARTICLE 18 - MISCELLANEOUS

18.1 Independent contractor status

The status of HHC and MGI under the business arrangement established by this agreement is that of independent contractors. MGI shall perform as an independent contractor in relation to both HHC and MGI's customers and, accordingly, MGI shall purchase the Products from HHC or HHC's nominee and resell them to its customers in its own name and for its own account. With the sole exception of the provisions of article 4.5 here above regarding MGI's role as HHC's FDA Agent, MGI has no authority whatsoever to act as an agent or representative of HHC nor any authority or power to contract in the name of or create any liability against or otherwise bind HHC in any way for any purpose, nor shall HHC have such authority or power to so bind MGI.

18.2 Notices

All reports, notices and communications given or made pursuant to thin Agreement by one Party to the other shall be validly given or made for all purposes, in the absence of acknowledgement of receipt, or the

date of nailing if nailed by registered airmail or by international courier to the addressee Party at the following addresses, respectively:

HELSINN HEALTHCARE SA
P.O. BOX 357
691S Pambio-Moranco
SWITZERLAND
For the attention of the Legal Department

MGI PHARMA INC.
6300 West Old Shakopee Road
Suite 110
Bloomington, MN 55438-7318
USA
For the attention of Manager, Legal Affairs

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with a copy to:

Dorsey & Whitney LLP
220 S. 6th Street
Minneapolis, MN 55402
Attention: Timothy S. Hearn

18.3 Binding Effect. Subject to the provisions of articles 2.1, 2.8 and 18.6 herein, this Agreement shall inure to the benefit of, and be binding upon, the respective successors of the Parties.

18.4 Waiver. The failure of a Party to insist upon strict performance of any of the terms and conditions of this Agreement by the other Party shall not constitute a waiver of any of the provisions hereof and no waiver by a party of any of said terms and conditions shall be deemed to have been made unless expressed in writing and signed by such waiving Party.

18.5 Interpretation.

18.5.1 The language of this Agreement is English. No translation into any other language shall be taken into account in the interpretation of the Agreement itself.

16.5.2 The headings in this Agreement are inserted for convenience only and shall not affect its construction.

18.5.3 Where appropriate, the terms defined in Article 1 hereabove and denoting a singular number only shall include the plural and vice versa.

18.5.4 References to any law, regulation, statute or statutory provision includes a reference to the law, regulation. statute or statutory provision as from time to time amended, extended or re-enacted.

18.6 Assignment. This Agreement and the licenses and other rights conferred upon MGI under this Agreement are personal to MGI and cannot be transferred, sublicensed, assigned or otherwise disposed of (by operation of law or otherwise) by MGI without the prior, written authorization of which authorization shall not be unreasonably withheld; provided, however, that MGI shall be entitled to assign this Agreement without such consent in connection with a merger, acquisition or sale of substantially all of its assets or to any of its Affiliates, in accordance however with the criteria established at Article 17.3 hereabove.

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HHC shall have the right to assign or transfer, in whole or in part, this Agreement to any of its Affiliates.

18.7 Statements to the Public. Neither HHC nor MGI shall make or procure or permit the making of any announcement or statement to the public with respect to This Agreement, its subject matter or any ancillary natter without the prior consent of the other Party, which consent shall not be unreasonably withheld.

The wording and the timing of any press release or of any other announcement and/or statement to the public shall have to be agreed upon in advance between the Parties.

Nothing herein shall prohibit MGI from disclosing information to the extent required by the U.S. securities and Exchange commission, Nasdaq or other similar authorities. It is however understood and agreed that (a) the contents of any copy of this Agreement, or of any other agreement between the Parties, which has to be sent to the SEC shall have to be previously agreed upon between the Parties and shall be in redacted form to maintain The confidentiality of proprietary and/or competitivity sensitive information, and (b) MGI shall use its best efforts to obtain authorization by the SEC to keep confidential any information which is deemed to be confidential by the Parties or any of them or which may, in either Party's opinion, put a competitive advantage to third parties.

18.8 Expenses. Unless specifically and expressly provided for to the contrary in this Agreement, each of the Parties shall bear its own expenses incurred in connection with the performance of this Agreement.

18.9 Survival. The following provisions shall survive expiration or termination of this agreement for any reason: Articles 1 (whole clause), 3.4, 4.2 (last

sentence), 4.7 (last sentence), 9.1, 11 (whole clause), 14 (whole clause), 17.6 through 17.8, 18 (whole clause), 27 (whole clause) and 21 (whole clause).

ARTICLE 19 -APPENDICES

19.1 The following Appendices shall be an integral part of this Agreement:

Appendix 1: List of Know-how Items

Appendix 2: Patents Appendix 3: Products

Appendix 4: Development Chart

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Appendix 5: HHC'S Post-Registration Regulatory Activities

Appendix 6: Adverse Events Reporting

Appendix 7: Products Recall Procedure

Appendix 8: Escrow Agreement

Appendix 9: MGI's unit sales base forecast - Annual Minimum sales

Appendix 10: Promotion and Marketing Activities

ARTICLE 20 - LAW TO GOVERN AND ARBITRATION

20.1 This Agreement shall be governed by and construed in accordance with the law of Switzerland

20.2 It is the express decision of the Parties that any dispute which may arise between the Parties concerning this Agreement, which cannot be settled amicably, shall be submitted to arbitration for final decision. Also, any dispute as to the applicability of the arbitration clause shall be subject to arbitration.

Notwithstanding the above, each Party expressly, reserves the right to seek judicial relief from a court of competent jurisdiction if the other Party is or appears to be in violation of such other Party's obligations of non use and non disclosure under Article 14 above, including, without limitation, any injunction or other preliminary relief.

20.3 It is expressly agreed that arbitration shall be held in English language in Genova (Switzerland), and conducted under the Rules of Arbitration of the international Chamber of Commerce. The court of arbitration shall consist of three arbitrators. Each Party is entitled to nominate one arbitrator. If, within one month after receipt of the request for arbitration filed by one Party, the other has not yet appointed an arbitrator, such arbitrator shall be appointed by the International Court of Arbitration of the international chamber of commerce on request of the first Party. The two arbitrators shall nominate the president of the court of arbitration, who shall be a lawyer qualified to practice and currently practicing as an attorney-at-law or as a judge. If they cannot come to terms within one month, the president of the court of arbitration shall be nominated by the International Court of Arbitration of the International Chamber of Commerce, on request of the more diligent Party.

20.4 If one of the arbitrators is unable to fulfil his/her duties for any reason the Party having nominated him/her shall nominate another arbitrator within one month, otherwise this

arbitrator will be nominated by the International Court of Arbitration of the International Chamber of Commerce.

20.5 If the arbitrators or the president have to be replaced, the proceedings do not have to be started anew and will continue at the point where they were stopped.

20.6 The court of arbitration is hereby expressly instructed to act with most diligence and to keep any term as short as possible and to render the decision as soon as possible.

20.7 The Parties hereby stipulate that any arbitration hereunder shall be subject to the following rules; (a) the arbitrators may not award or assess punitive damages against either Party; and (b) each Party shall bear its own costs and expenses of the arbitration and one-half (1/2) of the fees and costs of the arbitrators, subject to the power of the arbitrators, in their sole discretion, to award all such reasonable costs, expenses and fees to the prevailing Party.

20.8 The Parties agree that the arbitrator's award shall be the sole and exclusive remedy between them regarding any claims, counter-claims, issues or accountings presented or pled to the arbitrator and that any costs, fees or taxes incident to enforcing the award shall be, to the maximum extent permitted by law, charged against the Party resisting such enforcement.

20.9 Notwithstanding the foregoing, any Party may bring a case of action against the other Party before any court of competent jurisdiction at the domicile of the defendant Party, if and to extent that any arbitral award rendered in the arbitration proceedings is unenforceable.

20.10 subject to the provisions of Article 20.9. in the event that an award is rendered pursuant to this Article 20 by an arbitrator in favor of HHC, the Parties acknowledge and agree that such award shall be enforceable by HHC, and MGI hereby consents to the exclusive jurisdiction for purposes of enforcement of any such award against MGI to the United States District Court for the District of Delaware, or, if jurisdiction or venue cannot be laid therein, the jurisdiction of any courts in the state of Delaware. Each of the Parties hereby consents to the exclusive jurisdiction of such courts (and of the appropriate appellate courts) for the purposes set forth above.

ARTICLE 21 - ENTIRETY OF AGREEMENT AND SEVERABILITY

21.1 This Agreement supersedes all prior agreements and understandings, whether oral or written, made by either Party or between the Parties and constitutes the entire agreement of

the Parties with regard to the subject matter hereof. This Agreement shall not be considered extended, cancelled or amended in any respect unless done so in writing and signed on behalf of the Parties hereto.

21.2 The Parties hereby expressly state that it is the intention of neither Party to violate any rule, law and regulations. If any provision of this Agreement is rendered invalid or unenforceable, the Parties agree to renegotiate such provision in good faith and to replace it with valid and enforceable provisions in such a way as to reflect as nearly as possible the intent and purpose of the original provision.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement in be executed in duplicate by their duly authorized officers.

For and on behalf of
HELSINN HEALTHCARE SA

/s/ Riccardo Braglia
Riccardo Braglia
Managing Director

/s/ Enrico Braglia
Enrico Braglia
Managing Director

For and on behalf of
MGI PHARMA, INC.

/s/ Charles N. Blitzer
Charles N. Blitzer
President and Chief Executive officer

/s/ Leon O. Moulder, Jr.
Leon O. Moulder, Jr.
Executive Vice President

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Exhibit 99.2

Supply and Purchase Agreement between HELSINN BIREX PHARMACEUTICALS LTD and MGI Pharma, INC.

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THIS AGREEMENT (hereinafter called "Agreement") is effective as of this 5th day of April 2001 (hereinafter called "Effective Date"), between HELSINN BIREX PHARMACEUTICALS LTD, a corporation organized and existing under the law of the Republic of Ireland and having its registered office at Damastown, Mulhuddart, Dublin 15, Republic of Ireland (hereinafter called "HBP") of the one part, and MGI PHARMA, INC., a corporation organized and existing under the law of the state of Minnesota, United States of America and having its registered office at 6300 West Old Shakopee Road, Suite 110, Bloomington, MN 55438-2318, USA (hereinafter coiled "MGI"), of the other part.

RECITALS

a. MGI carries on business as a pharmaceutical company and in particular for the purpose of this Agreement, has entered into a License Agreement (as hereinafter defined) with Helsinn Healthcare SA, Via Pian Scairolo, 6912, Pazzallo, Switzerland (hereinafter called "HHC") by means of which MGI has been licensed with the right to distribute, promote. market and sell the Products (as hereinafter defined) in the Territory and has undertaken to purchase the Products exclusively from a source indicated or approved in writing by HHC.

b. HBP carries on business as a pharmaceutical manufacturer and Trader and, in particular for the purpose of this Agreement, represents that it has been duly appointed by HHC as the supplier of the Products to MGI for the purpose of the sale of said Products by MGI.

c. The Parties agree that this preamble constitutes an integral part of this Agreement and all capitalized terms used in this preamble shall have the meaning as defined in Article 1 hereafter.

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants and conditions herein contained, the Parties hereby agree as follows:

ARTIGLE 1 - DEFINITIONS

The following terms as used in this Agreement have, unless the context clearly

1.1 "Accounting period" means the quarters ending 31st March, 30th June, 30th September and 31st December in each year throughout the term of this Agreement.

1.2 "Affiliate" means an organization that, whether now or in the future, controls, is controlled by or is under common control with a Party. For the purposes of this definition, the terms "controls," "controlled by," and "under common control with" as used with respect to any Party, means the possession (directly or indirectly) of fifty percent or more of the voting stock or other equity interest of a subject entity with the power to vote, or the power in fact to control the management decisions of such entity through the ownership of securities, by contract or otherwise.

1.3 "Compound" means the active pharmaceutical ingredient (3a5-2-[(5)-1-Azabicyclo[2.2.2]oct-3-yl]-2,3,3a,4,5,6-hexahydro-1-oxo-1H-benz[de]isoquinoline hydrochloride, having the generic name palonosetron hydrochloride (INN) for use in human medicine.

1.4 "FDA" means the U.S. Food and Drug Administration or any successor agency.

1.5 "License Agreement" means the license agreement entered into between MGI and HHC on April 6th, 2001 granting MGI the exclusive right to distribute. market and sell the Products in the Territory.

1.6 "Net Sale Price" means the gross sale price in local currencies of the Products in the Territory by MGI and/or its Affiliates, including any local affiliate in Canada, for arm's lenghth sales to any non-Affiliated third party less those normal and customary deductions made under Generally Accepted Accounting Principles at arrive at Product sales.

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

1.7 "Net Sales" means the gross sales in local currencies of all Products sold in the Territory by MGI and/or its Affiliates, including any local Affiliate in Canada, for arm's lenghth sales to any non Affiliated third party less those normal and customary deductions made under Generally Accepted Accounting Principles to arrive at Product sales. ***

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

1.8 "Parties" means HBP and MGI and "Party" means either of them as the context indicates.

1.9 "Products" means the pharmaceutical preparations for human use in I.V. dosage form, containing the Compound as an active ingredient, in the formulation which will be described in the Registration. The current formulation as submitted to the Food and Drug Administration of the United States of America in the IND 39,797 Amendment # 64 and to the Therapeutic Products Programme of Canada in the IND 9427-H0836-21C is described in the First Appendix hereto.

1.10 "Registration" means any official approval, or authorization by the competent regulatory authorities, which is legally, required to lawfully market the Products in the territory, including, without limitation, any governmental price approval or reimbursement approved under a national health insurance system.

1.11 "Syntex Agreement" means a license agreement between HHC and Syntex (U.S.A.) LLC dated 23rd June 1998 by means of which HHC in-licensed world-wide rights on the compound and Products.

1.12 "Territory" means the United States of America and its possessions and territories (Puerto Ricom United Stares Virgin Islands), and canals and its provinces, possessions and territories.

ARTICLE 2 - PURCHASE OF PRODUCTS

2.1 Throughout the term of this Agreement, and subject to the terms and conditions contained herein, MGI undertakes to purchase exclusively from HBP, and HBP undertakes to sell to MGI. MGI's entire requirements of the Products to be distributed, promoted, marketed and sold by MGI or MGI's Affiliates under the License Agreement.

2.2 MGI shall not use the Products for any other purpose than distributing, promoting, marketing and selling said Products in accordance with the terms and conditions of the License Agreement.

ARTICLE 3 - PRICE AND TERMS OF PAYMENT

3.1 The price of the Products purchased by MGI hereunder is as set Forth in the Second Appendix hereto. ***

3.2 Any payment by MGI for the delivered Products shall be effected by wire transfer of immediately available funds to an account designated in writing by HBP in United States Dollars within 30 (thirty) days from the date of receipt of the invoice (which shall be deemed to have been received on the date following the date of delivery to MGI by telefax) and be deemed paid when freely received. MGI shall bear all costs in connection with effecting payments.

3.3 MGI shall in no case be entitled to off set or otherwise withhold any Payment due to HBP in view of possible, justified or unjustified, claims against HBP.

3.4 ***

ARTICLE 4 - FORECASTS. ORDERS AND TERMS OF DELIVERS

4.1 MGI shall, prior to September 30th in each year throughout the term of this Agreement, supply HBP in writing with a purchase forecast for the Products for each Accounting Period of the following calendar year. Any such forecast shall be deemed to be a binding order by MGI for the first Accounting Period ***

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

of such year. Moreover MGI shall issue its firm orders relevant to the three following Accounting Periods at least 90 (ninety) days in advance of the requested delivery date and, at each time, it shall supply HBP with its purchase forecast relevant to a further calendar year so as to maintain at all tines a rolling twelve-month purchase forecast and shall promptly notify HBP of any projected changes thereto.

4.2 The Products will be supplied to MGI only against MGI's written order and all orders shall be subject to written acceptance and confirmation by HBP before becoming binding. Such acceptance and confirmation may be by facsimile or otherwise. Each order by MGI shall be for a minimum quantity corresponding to the size of one production batch of Products, as shall be indicated in due time by HBP, or multiples thereof.

HBP shall use commercially reasonable efforts to execute all orders received and accepted pursuant to this article within 90 (ninety) days from the date of receipt of the relevant order by HBP. MGI's firm Orders shall be at least *** and not more than *** of its forecast of Products for the applicable Accounting Period as per Article 4.1 hereabove. HBP shall not be obliged to supply more than *** of MGI's initial forecast of Products within the applicable Accounting Period. However, in the event that, in any Accounting Period, MGI's orders are more than *** of the relevant forecasts, HBP agrees to use commercially reasonable efforts to supply MGI with amounts in excess of MGI's forecast of Product during said Accounting Period, on condition however that this shall not hamper, delay or otherwise prejudice supplies of Products to any other of HBP's customers. MGI shall keep throughout the term of this Agreement a stock of Products adequate to meet market demand and to cover possible shortages in the supplies of Products, such stock to approximately correspond at least to three-month average sales. In turn, HBP undertakes to keep throughout the term of this Agreement a stock of Products in semi-finished form (i.e. vials without final packaging) approximately corresponding to at least to two-month average sales.

4.3 Any purchase order or acknowledgement thereof, whether printed, stamped, typed or written, shall be governed by the terms and conditions of this Agreement and none of the provisions of such purchase order or acknowledgement thereof shall be applicable, except those specifying quantity

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with

the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

ordered, delivery dates and invoice information, and with respect to those specifications only to the extent that they are in compliance with the terms and conditions of this Agreement. To the extent there is any discrepancy between this Agreement and any purchase order or acknowledgement thereof, this Agreement will control.

4.4 All orders of Products shall be delivered DDU (Incoterms 2000) MGI's or MGI nominee's warehouse in the United States of America, unless otherwise agreed in writing by the Parties. MGI shall be solely responsible for all customs clearance of, and import/ export regulations for, the Products and it shall bear and pay all taxes, duties, levies and other charges imposed by reason of its purchase, import and resale of the Products.

4.5 If, for any reason, HBP is unable to supply MGI's firm orders for the Products up to the forecasted level, or is unable to supply such quantities in a manner meeting the specifications, during any ninety (90) day period, the Parties shall promptly meet to discuss the reasons for such failure to supply, and HBP shall thereafter designate in third party manufacturer to manufacture the Products. HBP shall provide to such third party manufacturer, appropriate manufacturing licenses and reasonable technical assistance to enable it to manufacture the Products, in a manner that minimizes disruption to MGI of Product supply.

ARTICLE 5 - QUALITY

5.1. HBP shall manufacture, or shall cause the Products to be manufactured, in accordance with applicable current mood manufacturing Practice and with applicable specifications.

5.2 Each batch of Products shall be delivered to MGI accompanied by appropriate certificates of analysis, attesting the compliance of each relevant batch with the specifications for said Products as the same are contained in the Registration of the Products. MGI shall carry out appropriate visual inspection of the products, as well as any other analysis which MGI may deem appropriate or necessary, upon receipt. Should it occur that any batch of Products does not meet said approved specifications, MGI shall, as soon as possible and in any case within 30 (thirty) days after receipt of the Products, give notice in writing to HBP specifying in detail the claimed non-conforming characteristics of the Products.

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In the absence of MGI's notification within the said term, MGI shall be deemed to have accepted such Products. Should HBP recognize that such Products delivered to MGI do not meet the approved specifications, and provided MGI demonstrates that the Products have been properly handled and stored after delivery, HBP shall replace, at its own cost, such Products. Such replacement shall be done, to the extent possible, in accordance with the timing reasonably agreed among the Parties which, in any event, shall be as soon as reasonably possible thereafter. It is u derstood and agreed that HBP's

total responsibilities hereunder shall be limited to said replacement of Products. Should HBP not be in agreement with MGI's claim of defect, a sample of the alleged defective Products shall be submitted for analysis to an independent laboratory to be agreed in good faith between MGI and HBP in writing. The decision of such laboratory shall be final and binding for both MGI and HBP and the corresponding expenses will be paid by the Party found to be in error.

5.3 HBP shall at any time be free to determine the manufacturer and the place of manufacture of the Products, subject however to applicable laws and regulations and to compliance with the License Agreement. In no event shall MGI be entitled to manufacture any Products by virtue of this Agreement.

5.4 MGI shall store and distribute, and shall cause the Products to be stored and distributed, according to applicable current Good Manufacturing Practice or any other applicable laws and regulations. MGI shall permit HBP's representatives, during normal business hours and upon three business days advance notice in writing but not more than once a year or as otherwise reasonably requested by HBP, to inspect those areas of the warehouses of MGI, its Affiliates and its distributors where the Products are inspected, analyzed or stored, for the purpose of verifying compliance with applicable laws and regulations as well as with this Agreement. Such inspection shall include, without limitation, the right to examine any relevant internal procedures or records of MGI, its Affiliates and distributers. MGI shall give and shall cause its Affiliates and distributors to give, all necessary assistance for a full and correct carrying out of the inspection by HBP. No such inspection by HBP shall

relieve MGI, its Affiliates and distributors of any of their obligations under this Agreement in any way whatsoever.

5.5 The products shall be supplied by HBP or HBP's nominee to MGI in a secondary package inclusive of leaflet, ready for distribution. Artwork and all necessary films for printing packs, package inserts, leaflets and labels will be

prepared and supplied by MGI, at its expenses, based upon indications, box design anti measurements provided by HBP. Any change shall have to be communicated by MGI to HBP at least 6 (six) months in advance of its enforcement. The costs relevant to the change, including costs relevant to repackaging or disposal of Products in stock at HBP, (i) shall be entirely borne by MGI if the change has been requested by MGI, and (ii) shall be shared between the parties in case the change is required by any regulatory authority or is jointly deemed advisable by the Parties.

5.6 Events concerning Product recall, complaint, field alert or product withdrawal relevant to the Products marketed by MGI in the Territory shall be governed by the procedures and rules established in the Licence Agreement.

ARTICLE 6 - RECORDS AND REPORTS

6.1 MGI shall submit to HBP at the end of each Accounting Period a written statement signed by a responsible officer of MGI which shall show the units of Products sold or otherwise disposed of by MGI, the gross sale price and the Net Sale Price of the Products

and any change thereof, together with a detailed listing and appropriate evidence or any and all discounts granted for each client, wholesaler and/or distributor as necessary to permit to HBP to calculate and verify the supply price of the Products as per the second Appendix hereto, the gross sales and the Net Sales for said Accounting Period and the existing stock of Products in MGI's, its Affiliates' and its distributors' warehouse. Throughout the term of this Agreement and for a period of at least 3 (three) years thereafter, MGI shall keep complete and accurate books, records and accounts in accordance with sound accounting practice covering all its operations hereunder as necessary to determine and verify the units of Products sold or otherwise disposed of by MGI, the Net Sale Price of the products, the Net Sales for each Accounting Period, and any change thereof. HBP shall have the right, at any time throughout the term of this Agreement and for a period of three years thereafter, during normal business hours and upon at least three (3) business days advance notice, to have such books, records and accounts inspected and audited by its duly authorized representatives or, at HBP's discretion, by an independent certified public accountant to be nominated by HBP and reasonably acceptable to MGI. MGI shall fully co-operate with HBP, its authorized representatives or independent certified public accountant and make available all work papers and other information reasonably requested in

connection herewith. In the event the inspection or audit reveals that an underpayment has occurred, MGI shall immediately pay to HBP any underpaid amount within 10 (ten) days of the date HBP delivers

to MGI the relevant inspection or audit report. In case of an underpayment of at least five percent (5%) of the amounts owing during the audited period, MGI shall also bear all the costs of the inspection or audit and any overdue amounts hereunder shall bear interest at the prime rate applicable in Switzerland as of the date such payment was originally due.

6.2 Each of the Parties hereby agrees that any and all communications sent to or received from the other Party hereunder, including but not limited to those described at Article 13.2 hereunder, shall be immediately sent in copy by telefax to HHC.

ARTICLE 7 - REPRESENTATIONS AND WARRANTIES

7.1 HBP hereby represents and warrants to MGI as follows:

7.1.1 HBP has been duly organized and is validly existing as a corporation in good standing under the laws of the Republic of Ireland. HBP has the corporate power and authority to enter into this Agreement and to consummate the transactions contemplated by this Agreement,

7.1.2 The execution, delivery and performance of this Agreement, and the consummation of the transactions contemplated by this Agreement, by HBP have been duly and validly authorized by all requisite corporate actions. This Agreement constitutes a legal, valid and binding agreement of HBP enforceable against HBP in accordance with its terms.

7.1.3 The execution, delivery and performance by HBP of this Agreement requires no action by or in respect of, or consent or approval of, or filing with, any Governmental Authority.

7.1.4 The execution, delivery and performance by HBP of the contemplated transactions do not and will not (A) contravene or conflict with the charter or bylaws of HBP, as applicable, (B) contravene or conflict with or constitute a violation of any provisions of any applicable law binding upon HBP or (C) constitute a default in any material respect under or give rise to any right of termination, cancellation or acceleration of, any

agreement or instrument to which HBP is a party, or to a loss of any material benefit to which HBP is entitled.

7.1.5 There is no action, suit, investigation or proceeding pending against, or to the knowledge of HBP, threatened against or affecting, HBP before any court, arbitrator or any governmental authority, including but not limited to Regulatory Authorities, that in any manner challenges or seeks to prevent, enjoin, alter or materially delay the contemplated transactions, and, to the knowledge of HBP, there is no reasonably valid basis for any such action, suit, investigation or proceeding to be brought.

7.1.6 The persons executing this Agreement on behalf of HBP are duly authorized to do so and by so going have bound HBP to the terms and conditions of this Agreement.

7.1.7 HBP has been duly authorized and entrusted by HHC to supply the Products to MGI.

7.2 MGI hereby represents and warrants to HBP as follows:

7.2.1 MGI is a corporation duly incorporated, validly existing and in good standing under the laws of the state of its incorporation and has all corporate powers and all governmental licenses, authorizations, consents and approvals required to carry on its business as now conducted and as contemplated to be conducted in connection with the transactions contemplated by this Agreement (the "Contemplated Transactions"). MGI is duly qualified to do business as a foreign corporation in each jurisdiction where the character of the property owned or leased by it or the nature of its activities (after giving effect to the Contemplated Transactions) make such qualification necessary to carry on its business, except where the failure to so qualify would not have a material adverse effect on MGI.

7.2.2 The execution, delivery and performance by MGI of this Agreement and the consummation by MGI of the Contemplated Transactions are within the corporate powers of MGI, and have been duly authorized by all necessary corporate action on the part of MGI. This Agreement constitutes a legal, valid and binding agreement of MGI, enforceable against MGI as applicable in accordance with its terms.

7.2.3 The execution, delivery and performance by MGI of this Agreement requires no action by or in respect of, or consent or approval of, or filing with, any Governmental Authority, other than filings with the

SEC in fulfillment of slot's disclosure obligations under U.S. securities laws,

7.2.4 The execution, delivery and performance by MGI of the Contemplated Transactions do not and will not (A) contravene or conflict with the charter or bylaws of MGI, as applicable, (B) contravene or conflict with or constitute a violation of any provisions of any Applicable Law binding upon MGI or (C) constitute a default in any Material respect under or give rise to any night of termination, cancellation or acceleration of, any agreement or instrument to which MGI is a party, or to a loss of any material benefit to which MGI is entitled.

7.2.5 There is no action, suit, investigation or proceeding pending against, or to the knowledge of MGI, threatened against or affecting, MGI before any court, arbitrator or any governmental authority, including but not limited to regulatory authorities, that in any manner challenges or seeks to prevent, enjoin, alter or materially delay the Contemplated Transactions, and, to the knowledge of MGI, there is no reasonably valid basis for any such action, suit investigation or proceeding to be brought.

7.2.3 The persons executing this Agreement on behalf of MGI are duly authorized to do so and by so doing have bound MGI to the terms and conditions of this Agreement.

ARTICLE 8 - INDEMNITIES AND INSURANCE

8.1 MGI shall be fully liable for and shall defend, indemnify and hold HBP and its Affiliates, officers, directors and employees wholly free and harmless from and against any and all liabilities, damages, losses, costs, taxes, expenses (including reasonable attorneys' fees and other expenses of litigation and

arbitration), claims, demands, suits, penalties, judgements or administrative and judicial orders arising out of or resulting from any claim, suit or proceeding to the extent arising out of or resulting from (a) any failure by MGI, its local distributors or Affiliates to comply with any applicable laws, regulations and/or administrative decision regarding the Products: (b) the storage, distribution, sampling, record-keeping, analysis transfer or sale of the products (c) the promotion, advertising and marketing of the Products; (d) the failure of any Products supplied hereunder to comply with the applicable approved specifications that (i) could have been detected by MGI carrying out visual inspection on the supplied Products with ordinary diligence or (ii) results from

any Products which have been altered, changed, packed or re-packed, processed or otherwise treated other than in strict accordance with HBP's instructions and specifications; or (e) any negligent or wrongful act or omission and/or any breach by MGI or by any of its local distributors and/or Affiliates of any of MGI's obligations, representations and/or warranties hereunder.

8.2 HBP shall be liable for and shall defend, Indemnify and hold MGI and its Affiliates, officers, directors and employees free and harmless from and against any and all liabilities, damages, losses, costs, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgments or administrative and judicial orders, arising out of or in any way resulting from any claim, suit or proceeding to the

extent arising out of or resulting from (a) failure of any Products supplied hereunder to conform to the applicable approved specifications, excluding however any liabilities, losses, damages, costs, expenses claims, demands, suits, penalties, judgments or orders resulting from any such non-compliance that (i) could have been detected by MGI carrying out visual inspections on the supplied Products with ordinary diligence or (ii) results from any Products which have been altered, changed, packed or re-packed, processed or otherwise treated other than in strict accordance with HBP's instructions and specifications' or (b) any negligent or wrongful act or omission and/or breach by HBP of any of its obligations and/or warranties hereunder,

8.3 Being understood that each of the parties hereto shall take all reasonable steps to avoid or mitigate any loss, damage or liability which might give rise to a claim under this Agreement, a Party seeking indemnification pursuant to this Article 8 (an "Indemnified Party") shall give prompt and full written notice to the Party from whom such indemnification is sought (the "Indemnifying Party") of the assertion of any claim, or the commencement of any action, suit or proceeding in respect of which indemnity is or may be sought hereunder, provided however that no failure to give such notice or co-operation shall relieve the Indemnifying Party of any liability and/or obligation hereunder (except to the extent the Indemnifying Party has suffered actual prejudice thereby). Subject to any right of Syntex (U.S.A.) LLC under the Syntex Agreement, the Indemnifying Party shall have the sole right to control the defense and settlement thereof, the Indemnified Party will give the Indemnifying Party such information with respect thereto as the Indemnifying Party may reasonably request and will co-operate with the Indemnifying Party in the

defense of said claim, suit or proceeding as the Indemnifying Party may

reasonably request. The Indemnified Party shall not, except at its own cost, voluntarily make any payment or incur any expense with respect to any claim suit or proceeding without the prior written consent of the Indemnifying Party. In addition, the Indemnifying Party shall be subrogated to the rights of the Indemnified Party against any third party, and such Indemnified Party hereby assigns to the Indemnifying Party all claims, causes of action and other rights which the Indemnified Party may then have against any third party, including Affiliates and in the case of HBP, against any contract manufacturer of the Products, with respect to the claim, suit or proceeding which is the subject of the claim for indemnification hereunder. Conversely, and without in any way limiting the obligation of either Party to indemnify the other Party as herein provided, to the extent that either Party shall fail to perform its indemnification obligations under this Article 8, such Party owing a duty of indemnification hereby assigns to the other Party all claims, cause of action and other rights which the Party owing such duty may when have against any third party, including Affiliates and, in the case of HBP, against any contract manufacturer of the Products, with respect to the claim, suit or proceeding.

8.4 MGI shall be solely responsible towards its customers for handling all matters concerning the Products, subject to cooperation with HBP on any recall or other matters that may be injurious to HBP. MGI shall be responsible for any expired Products,

whether stored by MGI and/or its local distributors or returned by wholesalers, pharmacists, doctors, hospitals to whom said products have been sold. HBP shall (i) reimburse to MGI documented reasonable costs incurred by MGI with regard to the destruction of expired Products, up to a maximum quantity of *** of the units of Products sold by MGI in any calendar year and (ii) replace free of charge said expired Products, up to a maximum quantity of *** of the units of Products sold by MGI in any calendar year. Except as provided hereabove, MGI shall not be entitled to any replacement of Products nor to any compensation of any kind from HBP in connection herewith. MGI shall indemnify, defend and hold HBP and its Affiliates, directors, officers and employees wholly free and harmless from and against any and all liabilities, damages, losses, costs, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgments or administrative and judicial orders arising therefrom: except with respect to any recall or other regulatory action arising from any breach by HBP or its Affiliates of any warranty, representation or other material obligation contained in this Agreement or the negligence or willful misconduct, of HBP or its Affiliates.

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange act of 1934.

8.5 Each party shall indemnify and hold the other Party wholly harmless from and against any and all liabilities, damages, losses, costs, expenses (including reasonable attorneys' fees and other expenses of litigation and arbitration), claims, demands, suits, penalties, judgments or administrative and judicial orders arising out of any behavior contrary or in excess to the provisions of Article 13.1 hereunder.

8.6 THE SOLE REPRESENTATIONS AND WARRANTIES THAT HBP MAKES WITH RESPECT TO THE MATTER CONTEMPLATED BY THIS AGREEMENT ARE EXPRESSLY SET FORTH IN ARTICLE 7.1. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, HBP MAKES NO REPRESENTATION OR WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, OF MARKETABILITY, CAPACITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE PRODUCTS. NO ORAL OR WRITTEN REPRESENTATION BY OR ON BEHALF OF HBP SHALL BE INTERPRETED TO CONTAIN ANY SUCH WARRANTY. NEITHER MGI NOR ANY OF ITS EMPLOYEES OR REPRESENTATIVES IS AUTHORISED TO GIVE ANY WARRANTIES OR MAKE ANY REPRESENTATION ON BEHALF OF HBP.

8.7 THE SOLE REPRESENTATIONS AND WARRANTIES THAT MGI MAKES WITH RESPECT TO THE MATTER CONTEMPLATED BY THIS AGREEMENT ARE EXPRESSLY SET FORTH IN ARTICLE 7.2. AND MGI HEREBY DISCLAIMS ALL OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED. NO ORAL OR WRITTEN REPRESENTATION BY OR ON BEHALF OF MGI SHALL BE INTERPRETED TO CONTAIN ANY SUCH WARRANTY. NEITHER HBP

NOR ANY OF ITS EMPLOYEES OR REPRESENTATIVES IS AUTHORISED TO GIVE ANY WARRANTIES OR MAKE ANY REPRESENTATION ON BEHALF OF MGI.

8.8 NOTWITHSTANDING ANY OTHER PROVISION OF THIS AGREEMENT, NEITHER OF THE PARTIES SHALL BE LIABLE TOWARDS THE OTHER FOR INDIRECT, SPECIAL, PUNITIVE, EXEMPLARY, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION LOSS OF PROFITS OR REVENUES, REGARDLESS OF WHETHER SUCH DAMAGES HERE FORESEEABLE OR NOT. THIS CLAUSE WILL HOWEVER NOT BE APPLICABLE IN CASE OF BREACH BY MGI OF THE PURCHASE OBLIGATIONS STATED AT ARTICLE 2 AND BREACH BY EITHER

PARTY OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS STATED AT ARTICLE 9 OF THIS AGREEMENT.

8.4 Each Party agrees to procure and maintain in full force and effect during the term of this Agreement valid and collectible insurance policies in connection with its activities as contemplated herein. In particular, MGI at its own cost shall cause HBP to be added as additional named insured throughout the term of this Agreement on all policies of general commercial liability insurance and product liability insurance covering MGI, which coverage shall, when MGI either initiates clinical trials on the Products or begins marketing or distributing the Products for commercial sale or for promotional purposes, have limits of

liability which are commercially reasonable in the Territory but shall be not less than USD *** per loss occurrence, within 5 (five) days of the Effective Date and of each beginning of each policy period, MGI shall provide HBP With a certificate evidencing the coverage required hereby and the amount thereof. Such coverage shall be with a reputable insurance company having at least an A.M, Best "A" rating and shall have to be maintained for not less than 6 (six) years following expiration or termination of this Agreement for any reason or if such coverage is of the "claims made" type, for ten years following expiration for termination of this agreement for any reason.

ARTICLE 9 - CONFIDENTIALITY

9.1 MGI shall treat as strictly confidential, and shall use solely for the purpose of and in accordance with this Agreement. any and all information, data and/or document received hereunder or in connection with the Contemplated Transaction not generally known to the trade (all hereinafter referred to as the "Confidential Information"). MGI shall not make such Confidential Information available to any third Party, including any of its Affiliates, except to competent government agencies to which it will be necessary to disclose such information, and in this case (a) strictly to the extent requested by said agencies and (b) only upon exercise of its best efforts to cause said agencies to maintain confidentiality thereof.

9.2 Such Confidential Information shall only be made available to such employees of MGI who are directly and necessarily involved in the authorized use of Confidential Information and who are subject to a secrecy obligation by ***

*** Denotes confidential information that has been omitted from the exhibit and filed separately, accompanied by a confidential treatment request, with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934.

contract, to the extent strictly necessary to perform their duties and obligations hereunder,

9.4 Notwithstanding expiration or termination of this Agreement for any reason, these confidentiality and non-use obligations shall continue until the Confidential Information has become generally known to the public, provided however that nothing contained herein shall in any way restrict or impair the right of MGI to use, disclose or otherwise deal with Information which MGI can demonstrate to HBP by clearly convincing documentation:

9.3.1 is or hereafter becomes part of the public domain through no act or omission of MGI, its employees, Affiliates and/or local distributors, or

9.3.2 MGI was in lawful possession of prior to receipt of the confidential information from HBP, or

9.3.3 previously was, or at any time hereafter is, received in good faith by MGI from sources other than HBP, and/or HHC and which did not originate, directly or indirectly, from Syntex, or

9.3.4 at the time of disclosure, was known by MGI or an Affiliate or local distributor, or after disclosure was independently developed by MGI, an affiliate or local distributor without use of the Confidential Information.

9.4 HBP shall keep strictly confidential, in the same any mutatis mutandis as provided here above for MGI in respect of confidential Information, any MGI confidential information (as defined herein) received from MGI hereunder, except as otherwise specifically provided in this Agreement. As used herein, the term "Confidential Information" shall mean all information disclosed by MGI to HBP, relating to the markets, customers, suppliers, patents or patent applications, inventions, know-how, data or information, products, research and development, procedures, designs, formulas, business plans, financial projections, employees, consultants or any other similar aspects MGI's present or future business, whether such information is disclosed in written, oral, electronic, graphic or other formal.

ARTICLE 10 - FORCE MAJEURE

10.1 Except as set Forth in Section 4.5, if the performance of this Agreement is prevented or restricted by government action, war, fire, explosion, flood, strike, lockout, embargo, act of God, or any other similar cause beyond the control of the defaulting Party, the Party so affected shall be released for the duration of the force majeure, or such other period agreed between the Parties as being reasonable in all circumstances, from its contractual obligations directly affected by the force majeure, provided that the Party concerned shall:

10.1.1 give prompt notice in writing to the ocher Party of the cause of Force majeure:

10.1.2 use all best endeavors to avoid or remove such cause of non-performance;

10.1.3 continue the full performance of this Agreement as soon as such Cause is removed.

10.2 The Parties shall take all reasonable steps to minimize the effects of force majeure on the performance of this Agreement and shall, if necessary, agree on appropriate measures to be taken. Should the force majeure continue for more than 6 (six) months, then the other Party shall have the right to terminate this Agreement forthwith.

10.5 Notwithstanding anything contained in this Article 10, obligations to pay money accruing prior to the force majeure event are never excused by Force majeure.

ARTICLE 11 - TERM

11.1 This Agreement comes into force at the Effective Date hereof, unless terminated earlier pursuant to the provisions hereof, it shall terminate automatically at termination or expiration for any reason of the License Agreement.

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ARTICLE 12 - TERMINATION

12.1 Each of the Parties reserves the right to terminate this Agreement in case of any substantial or persistent breach of any of the terms and conditions of this Agreement by the other Party. The defaulting Party shall be given in writing a 60 (sixty)-day period, except as otherwise specifically provided, to fulfill its obligations hereunder and, if after such period it is still in breach of the Agreement, the other Party shall

have the right to terminate this Agreement by written notice to the defaulting Party. In the event of a breach by MGI of any of the terms and conditions of this Agreement entitling HBP to terminate this Agreement under this Article 12.1, HBP shall immediately and fully inform HHC in writing for appropriate actions by HHC. In particular, MGI hereby acknowledges and agrees that termination of this Agreement by HBP pursuant to this Article 12.1 shall entitle HHC to terminate the License Agreement.

12.2 Either Party snail have the riot to terminate this Agreement upon written notice to the other Party, if such other Party shall become insolvent or shall make an assignment for the benefit of creditors or become involved in receivership, bankruptcy or other insolvency or debtor relief proceedings, or any similar proceedings, or in proceedings, voluntary or forced, whereby the Party involved is limited in the free and unrestrained exercise of its nor judgment as to the carrying out of the terms of this Agreement.

12.3 HBP shall have the right to terminate this Agreement by written notice to MGI if MGI infringes the confidentiality and/or non-use obligations provided for in Article 9 hereabove. MGI shall have the right to terminate this agreement by written notice to HBP if HBP breathes the confidentiality and/or non-use obligations provided for in Article 9.4 hereabove.

12.4 Without limiting the generality of the foregoing, termination or expiration of this Agreement for any reason shall not extinguish any existing claims either of the Parties may have for indemnification and shall not preclude either of the Parties from pursuing any claim for indemnification such Party otherwise may have to the extent that the circumstances giving

rise to such claim arose prior to, on or after the date of termination or expiration.

12.5 Upon expiration or termination of this Agreement for any reason, MGI shall promptly terminate using any and all information and data received hereunder

and return or deliver all such materials to HBP without retaining copies, notes, summaries or translations thereof.

12.6 Unless otherwise set forth herein, the Parties' remedies under this Agreement are intended to be cumulative and net motually exclusive.

ARTICLE 13 - MISCELLANEOUS

13.1 Independent contractor status

The status of HBP and MGI under the business arrangement established by this Agreement is that of independent contractors. MGI shall perform as an independent contractor in relation to both HBP and MGI's customers and. accordingly, MGI shall purchase the Products from HBP or HBP'S nominee and resell then to its customers in its own name and for its own account. MGI has no authority whatsoever to act as an agent or representative of HBP nor any authority or power to contract in the name of or create any liability against or otherwise bind HBP in any way for any purpose, nor shall HBP have such authority or power to so bird MGI.

13.2 Notices

All reports, notices and communications given or made pursuant to this Agreement by one Party to the

other shall be validly given or made for all purposes, in the absence of acknowledgement of receipt, on the date of mailing if mailed by registered airmail or by international courier to the addressee Party at the following addresses, respectively:

HELSINN BIREX PHARMACEUTICALS LTD.
Damastown
Mulhuddart
Dublin 15
Republic of Ireland
For the attention of: General manager

With copy to:

HELSINN HEALTHCARE SA
P.O. BOX 357
6915 Pambio-Noranco
SWITZERLAND
For the attention of regal Department

MGI PHARMA INC.
6300 West Old Shakopee Road
Suite 110
Bloomington
MN 55438-2318, USA
For the attention of: Manager, Legal Affairs

With copy to:

Dorsey & Whitney LLP
220 South Sixth Street
Minneapolis, MN 55402
For the attention of: Timothy S. Hearn

13.3 Binding Effect

Subject to the provisions of article 13.6 herein, this Agreement shall inure to the benefit of, and be binding upon, the respective successors of the Parties.

13.4 Waiver

The failure of a Party to insist upon strict performance of any of the terms and conditions of this Agreement by the other Party shall not constitute a waiver of any of the provisions hereof and no waiver by a Party of any of said terms and conditions shall be deemed to have been made unless expressed in writing and signed by such waiving Party.

13.5 Interpretation

13.5.1 The language of this Agreement is English. No translation into any other language shall be taken into account in the interpretation of the agreement itself.

13.5.2 The headings in this Agreement are inserted for convenience only and shall not affect its construction.

13.5.3 Where appropriate, the terms defined in Article 1 hereabove and denoting a singular number only shall include the plural and vice versa.

13.5.4 References to any law, regulation, statute or statutory provision includes a reference to the law, regulation, statute or statutory provision as from time to time amended, extended or re-enacted.

13.6 Assignment

This Agreement cannot be transferred, sublicensed, assigned or otherwise disposed of (by operation of law or otherwise) by MGI without the prior, written authorization of HBP, which authorization shall not be unreasonably withheld, provided however that MGI shall be entitled to assign this Agreement in conjunction with the assignment of the License Agreement in accordance with the terms and conditions thereof, HBP shall have the right to assign or transfer, in whole or in part, this Agreement to any of its Affiliates.

13.7 Statements to the Public

Neither HBP nor MGI shall make or procure or permit the molting of any announcement or statement to the public with respect to this Agreement its subject matter or any ancillary ratter without the prior consent of the other Party, which consent shall not be unreasonably withheld. The wording and the timing of any press release or of any other announcement and/or statement to the public shall have to be agreed upon in advance between the Parties.

Nothing herein shall prohibit MGI from disclosing information to the extent required by the U.S. Securities and Exchange Commission, Nasdaq or other similar authorities. It is however understood and agreed that (a) the contents of any copy of this Agreement, or of any other agreement between the Parties, which has to be sent to the SEC shall have to be previously agreed upon between the Parties and shall be in redacted form to maintain the confidentiality of proprietary and/or competitivity sensitive information, and (b) MGI shall use its best efforts to obtain authorization by the SEC to keep confidential any information which is deemed to be

confidential by the Parties or any of than or which may, in either Parry's opinion, put a competitive advantage to third parties.

13.8 Expenses

Unless specifically and expressly provided for to the contrary in this Agreement, each of the Parties shall bear its own expenses incurred in connection with the performance of this Agreement.

13.9 Survival

The following provisions shall survive expiration or Termination of this Agreement for any reason: Articles 1 (whole clause), 6 (whole clause), 8 (whole clause), 9 (whole clause), 12.4 through 12.6, 13 (whole clause), 15 (whole clause) and 16 (whole clause),

ARTICLE 14 - APPENDICES

14.1 The following Appendices shall be an integral part of this Agreement:

Appendix 1: Products

Appendix 2: Price

ARTICLE 15 - LAW TO GOVERN An ARBITRATION

15.1 This Agreement shall he governed by and construed in accordance with the law of Switzerland.

15.2 It is the express decision of the Parties that any dispute which may arise between the Parties concerning this Agreement, which cannot be settled amicably, shall be submitted to arbitration for final decision. Also, any dispute as to the applicability of the arbitration clause shall be subject to arbitration.

Notwithstanding the above, each Party expressly reserves the right to seek judicial relief from a court of competent jurisdiction if the other Party is or appears to be in violation of such other Party's obligations of non-use and non-disclosure under Article 9 above, including, without limitation, any injunction or other preliminary relief.

15.3 It is expressly agreed that arbitration shall be held in English language in Geneva (Switzerland) and conducted under the Rules of Arbitration of the International Chamber of Commerce. The court of arbitration shall consist of three arbitrators. Each Party is entitled to nominate one arbitrator. If, within one month after receipt of the request for arbitration filed by one Party, the other has not yet appointed an arbitrator, such arbitrator shall be appointed by the International Court of Arbitration of the International Chamber of Commerce on request of the first Party. The two arbitrators shall nominate the president of the court of arbitration, who shall be a lawyer qualified to practice and currently practicing as an attorney-at-law or as a judge. If they cannot come to terms within one month, the president of the court of arbitration shall be nominated by the International Court of Arbitration of the International Chamber of Commerce, on request of the more diligent Party.

15.4 If one of the arbitrators in unable to fulfil his/her duties for any reason the Party having nominated him/her shall nominate another arbitrator within one month,

otherwise this arbitrator will be nominated by the international Court of Arbitration of the International Chamber of Commerce.

15.5 If the arbitrators or the president have to be replaced, the proceedings do not have to be started anew and will continue at the point where they were stopped.

15.6 The court of arbitration is hereby expressly instructed to act with most diligence and to keep any term as short as possible and to render the decision as soon as possible.

15.7 The Parties hereby stipulate that any arbitration hereunder shall be subject to the following rules: (a) the arbitrators may not award or assess punitive damages against either Party; and (b) each Party shall bear its own costs and expanses of the arbitration and one-half (1/2) of the fees and costs of the arbitrators, subject to the power of the arbitrators, in their sole discretion, to award all such reasonable costs, expenses and fees to the prevailing Party.

15.8 The Parties agree that the arbitrator's award shall be the sole and exclusive remedy between them regarding any claims, counter-claims, issues or accountings presented or pled to the arbitrator and that any costs, fees or taxes incident to enforcing the award shall be, to the maximum extent permitted by law, charged against the Party resisting such enforcement.

15.9 Notwithstanding the foregoing, any Party may bring a case of action against the other Party before any court of competent jurisdiction at the domicile of the defendant Party, if and to extent that any arbitral award rendered in the arbitration proceedings is unenforceable.

15.10 Subject to the provisions of article 15.9 in the event that an award is rendered pursuant to this Article 15 by an arbitrator in favor of HBP, the Parties acknowledge and agree that such award shall be enforceable by HBP, and MGI hereby consents so the exclusive jurisdiction for purposes of enforcement of any such award against MGI to the United States District Court for the District of Delaware, or, if jurisdiction or venue cannot be laid therein, the jurisdiction of any courts in the State of Delaware. Each of the Parties hereby consents to the exclusive jurisdiction of such courts (and of the appropriate appellate courts) for the purposes set forth above.

ARTICLE 16 - ENTIRETY OF AGREEMENT AND SEVERABILITY

16.1 This Agreement supersedes all prior agreements and understandings, whether oral or written, made by either Party or between the Parties and constitutes the entire Agreement of the Parties with regard to the subject matter hereof. The Parties however acknowledge and understand that (a) the existence and validity of this Agreement depend upon and are conditional upon the existence and validity of the License Agreement and (b) in case of any discrepancy between the License Agreement and this Agreement, this agreement shall be construed in a manner consistent with the License Agreement. This Agreement shall not be considered extended, cancelled or amended in any respect unless done so in writing and signed on behalf of the Parties hereto.

16.2 The Parties hereby expressly state that it is the intention of neither Party to violate any rule, law

and regulations. If any provision of this Agreement is rendered invalid or unenforceable, the Parties agree to renegotiate such provision it good faith and to replace it with valid and enforceable provisions in such a way as to reflect as nearly as possible the intent and purpose of the original provision.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate by their duly authorized officers.

For and on behalf of
HELSINN BIREX PHARMACEUTICALS Ltd

/s/ Riccardo Braglia
Riccardo Braglia
Proxy

/s/ Enrico Braglia
Enrico Braglia
Proxy

For and on behalf of
MGI PHARMA, INC.

/s/ Charles N. Blitzer
Charles N. Blitzer
President and Chief Executive officer

/s/ Leon O. Moulder, Jr.
Leon O. Moulder, Jr.
Executive Vice President

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Exhibit 99.3

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NEWS RELEASE

FOR IMMEDIATE RELEASE
March 22, 2001

CONTACT:
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MGI PHARMA INITIATES NEW PHASE 2 TRIAL OF IROFULVEN FOR OVARIAN CANCER

New Phase 2 Trial to Evaluate Every-Other-Week Dosing schedule

MINNEAPOLIS, March 22, 2001 – MGI PHARMA, INC., (Nasdaq: MOGN) today announced that it has initiated a new Phase 2 clinical trial of irofulven, its novel anticancer compound, for patients with refractory or recurrent advanced epithelial ovarian cancer. This multi-center phase 2 trial will evaluate irofulven using an every-other-week dosing schedule in up to 65 patients to develop recommendations for an anticipated Phase 3 trial with irofulven in advanced ovarian cancer. This trial is being conducted based in part upon the anti-cancer activity seen in trials sponsored by MGI and sponsored by the National Cancer Institute (NCI). Tumor shrinkage, including a complete response in the NCI Phase 2 ovarian cancer trial, and a complete response in an

ovarian cancer patient using the every other week dosing schedule in a dose optimization trial, have prompted further development of irofulven for the treatment of ovarian cancer. The intermittent, every-other-week dosing schedule for irofulven is being used based upon the greatly improved tolerance and demonstrated anti-cancer activity that was seen with this schedule in the dose optimization trial. The patient enrollment period for this Phase 2 trial is expected to last approximately 12-18 months.

"We are excited to further explore the activity that has been demonstrated in earlier trials of irofulven for ovarian cancer patients," said Dr. David S. Alberts, professor of medicine, pharmacology and public health and associate dean for research, College of Medicine and Arizona Cancer Center, University of Arizona and lead investigator for MGI's trial. "Because of the evidence and anti-tumor activity seen in ovarian cancer patients who have failed prior therapies, and because of the improved tolerance and diminished toxicity with the new dosing schedule, we are eager to determine irofulven's role in treating these patients."

Ovarian cancer is the leading cause of gynecological cancer deaths among women in the United States. The American Cancer society estimated that approximately 23,100 new cases of ovarian cancer were diagnosed and 14,000 women died from the disease in the U.S. in 2000. Worldwide, 166,000 new cases of ovarian cancer and 101,000 deaths are estimated to occur

annually. The current first-line treatment of advanced ovarian cancer consists mainly of surgery followed by combination chemotherapy consisting of paclitaxel (Taxol(R)) and carboplatin (Paraplatin(R)), the two most commonly prescribed drugs.

"Most ovarian cancer patients will eventually develop platinum- and paclitaxel-resistance, and salvage chemotherapy in this group is each into effective than first-line therapy," notes Dr. John MacDonald, MGI's senior vice president of research and development. "That's why chemotherapeutics with novel mechanisms of action, such as irofulven, are attractive agents to test against the drug-resistant tumors. The need for new agents in this area is huge, and we are focused on addressing these unmet needs of cancer patents."

Results of Irofulven in Ongoing Ovarian Cancer Trials

MGI PHARMA is studying irofulven in refractory ovarian cancer patients who have had tumor growth during their first-line treatment or within six months following that treatment. Interim results from MGI's ongoing Phase 2 trial of irofulven in ovarian cancer indicate that of the 78 patients evaluable for objective response:

- one patient achieved the primary endpoint of a confirmed partial response;
- one patient experienced a partial response that was observed in only the first of two

measurements required for a confirmed partial response; and

- one patient experienced stable disease and received four cycles of treatment.

The NCI is conducting a Phase 2 trial of irofulven for the treatment of ovarian cancer in patients with recurrent or persistent disease. Irofulven was administered daily for 4-5 days every 28 days, in a presentation at the annual meeting of the American Association of Cancer Research (AACR) in April 2000, the principal investigator for the MGI trial concluded that irofulven is an active agent an ovarian cancer patients with recurrent or persistent disease and that further studies are warranted. Interim results from the first 27 patients enrolled in the trial include the following:

- one patient achieved complete clinical response, the disappearance of measurable disease;
- five patients achieved the primary endpoint of a partial response, with two responses lasting more than one year; and
- Seven patients experienced stable disease, ranging up to nine months.

About Irofulven

Irofulven (also known as MGI 114, hydroxymethylacylfulvene, or HMAF) is the first product candidate being developed by MGI PHARMA from its family of proprietary anti-cancer compounds called acylfulvenes. Irofulven is currently being tested in a series of clinical trials for

the treatment of solid tumors, across a variety of cancers. Irofulven has demonstrated promising anti-tumor activity as a single agent in clinical testing against pancreatic, ovarian and prostate cancers. In February 2001, MGI PHARMA initiated a pivotal Phase 3 trial of irofulven in advanced-stage, refractory pancreatic cancer patients. side effects from irofulven are comparable to those seen with marketed chemotherapies and include bone marrow suppression (decreases in platelets or white blood cell counts), nausea, vomiting and fatigue. Patients and healthcare providers seeking information on the various irofulven clinical trials may call MGI PHARMA's medical communications Help Line at 1-850-562-5580 or the National Cancer Institute's Cancer Information Service at 1-800-4-CANCER (TTY 1-800-332-8615).

About MGI PHARMA

MGI PHARMA, INC. is an oncology-focused pharmaceutical company that acquires, develops and commercializes proprietary products that meet patient needs. MGI PHARMA focuses its sales efforts solely in the United States and collaborates with other pharmaceutical or biotechnology companies for its products in international markets. For more information about MGI PHARMA, please visit the company's web site at www.mgipharma.com.

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not guarantees of future performance and involve a number of risks and uncertainties that may cause the company's actual results to differ materially from the results discussed in these statements. Factors that might affect MGI PHARMA's results include, but are not limited to the ability of MGI PHARMA's product candidates, such as irofulven, to be proven safe and effective in humans and to ultimately compete successfully with other therapies, continued sales of MGI PHARMA's marketed products, development or acquisition of additional products, reliance on contract manufacturing, changes in strategic alliances, and other risks and uncertainties detailed from time to time in the Company's filings with the Securities and Exchange Commission. MGI PHARMA does not intend to update any of the forward-looking statements after the date of this news release to conform them to actual results.

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NEWS RELEASE

FOR IMMEDIATE RELEASE
March 28, 2001

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MGI PHARMA PRESENTS FURTHER DATA ON IROFULVEN'S ANTI-TUMOR ACTIVITY AT AACR MEETING

MINNEAPOLIS, March 28, 2001 – MGI PHARMA, INC., [Nasdaq: MOGN) today announced that six poster presentations on irofolven's anti-tumor activity and mechanism of action were made at this year's American Association for Cancer Research (AACR) meeting held in New Orleans from March 24 - 28, 2001. The preclinical data presented serves as the basis for MGI's plans to expand the clinical development of irofulven in a variety of cancers.

In one presentation, complete regressions of hormone-refractory human DU-145 prostate tumors growing in nude mice were reported when irofulven was used in combination with Taxotere(R) (docetaxel). complete regressions were observed in 17 of 20 animals administered the drugs in combination, whereas Taxotere alone produced no complete regressions and a submaximal dose of irofulven produced complete regressions in two of 10 animals. MGI now plans to initiate a Phase 1 clinical trial to evaluate this promising drug combination in cancer patients.

Another investigation reported on the activity of irofulven in combination with other anti-cancer agents in human tumor cell lines and drug-resistant human tumor xenografts. Irofulven combined with taxanes, topoisomerase I inhibitors, mitomycin C, thiotepa, or carboplatin exhibited statistically significant synergistic (or greater than additive) anti-tumor effects. Such activity suggests a basis for possible new clinical investigations.

Complete regressions were also reported following irofulven treatment of mice bearing glioblastoma xenografts. Glioblastoma is a particularly lethal form of brain tumor for which the limited treatment options provide minimal benefit. This investigation demonstrated the ability of irofulven to cross the blood-brain barrier in an active form. MGI also intends to initiate a Phase 2 trial to evaluate irofulven's activity in this particularly challenging tumor target.

Three additional presentations on irofulven's preclinical activity further characterize the mechanism by which irofulven induces apoptosis in human breast, prostate, and pancreatic tumor cell lines.

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About Irofulven

Irofulven (also known as MGI 114, hydroxymethylacylfulvene, or HMAF) is the first product candidate being developed by MGI PHARMA from its family of proprietary anticancer compounds called acylfulvenes. Irofulven is currently being tested in a series or clinical trials for the treatment of solid

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About MGI PHARMA

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EDITORS' NOTE: Abstracts presented on irofulven at AACR include:

#475 Antitumor Activity of Irofulven (MGI 114) in Combination with Taxotere against DU145 Human Prostate Tumor Xenograft model.

#476 Activity of Irofulven (MGI 114, HMAF) in Combination with other Chemotherapeutic Agents.

#1753 Activity of Irofulven (6-Hydroxymethylacylfulvene, MGI 114) in the Treatment of Human Central Nervous System Tumors Growing in Athymic Nude Mice.

#3443 Caspase 3 Is Not Required for Apoptosis by Irofulven (Hydroxymethylacylfulvene).

#3444 Irofulven-Induced Apoptosis in Human Pancreatic Cancer Cells is Mediated by Activation or ERK and JNK Kinases.

#3445 Early Events in Apoptosis Induced by Irofulven (Hydroxymethylacylfulvene) in Prostate Tumor Cells.

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Exchange Commission. MGI PHARMA does nor intend to update any of the forward-looking statements after the date of this news release to conform them to actual results.

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NEWS RELEASE

FOR IMMEDIATE RELEASE
April 10, 2001

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MGI PHARMA SIGNS EXCLUSIVE LICENSE AGREEMENT WITH HELSINN HEALTHCARE SA, FOR PALONOSETRON, A PHASE 3 ANTI-EMETIC

MINNEAPOLIS and LUGANO, SWITZERLAND, April 10, 2001 - MGI PHARMA, INC., (Nasdaq: MOGN) and Helsinn Healthcare SA, a privately owned pharmaceutical group with headquarters in Switzerland, today announced that they have signed the definitive agreement granting MGI PHARMA exclusive North American license and distribution rights to palonosetron. The signing of the letter of intent for this agreement was previously announced in February. Palonosetron is a potent and selective 5-HT3 antagonist with an extended half-life, in Phase 3 development for the prevention of chemotherapy-induced nausea and vomiting (CINV). Completion of the Phase 3 trials could allow for NDA. (New Drug Application) submission in the first half of 2002. When launched, palonosetron will compete in the $1 billion North American CINV market.

"We are looking forward to entering the supportive care segment of oncology, the successful completion of the Phase 3 program and approval process for palonosetron, and the opportunity to demonstrate the role that this novel agent can have in preventing chemotherapy-induced nausea and vomiting for cancer patients," commented Chuck Blitzer, president and CEO of MGI PHARMA. "Palonosetron is another exciting addition to our growing oncology product portfolio, representing another well-advanced product that can be commercialized in the near term."

"Palonosetron is our first product entry into the United States, and we are pleased to be working with MGI PHARMA for the North American distribution of this innovative product in the supportive care segment

of oncology," commented Riccardo Braglia, managing director of HELSINN. "We know that MGI PHARMA's proven commercial organization, its experienced oncology sales force, and its present and future commitment to palonosetron's role within the 5-HT3 antagonist marketplace will ensure the success of our new partnership."

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About Palonosetron

When launched as a marketed product, palonosetron will be one of four products competing in the $1 billion north American market for 5-HT3 antagonists. The extended half-life of palonosetron as compared to the other agents and the results of Phase 2 trials assessing efficacy beyond 24 hours differentiates Palonosetron from the three currently marketed 5-HT3 antagonists indicated for CINV.

CINV in estimated to occur in 85 percent of cancer patients undergoing chemotherapy and can result in delay or even discontinuation of treatment, and the advent of 5-HT3 antagonists has revolutionized the management of nausea and vomiting experienced by cancer patients undergoing chemotherapy.

Palonosetron has been tested in a randomized, double-blind dose-ranging Phase 2 Trial at multiple sites throughout the U.S. that evaluated its efficacy and safety when administered in a single intravenous dose for the prevention of nausea and vomiting in patients receiving highly emetogenic chemotherapy. over 1,000 patients have participated in Phase 3 and

Phase 2 trials of palonosetron. Based on these results, Helsinn initiated a Phase 3 clinical trial program that is intended to enroll more than 1,900 patients in several well-controlled, double-blind trials comparing palonosetron to currently available 5-HT3 antagonists - at approximately 80 centers in North America and Europe. Based on the extended half-life of palonosetron and the results of the Phase 2 trial, its efficacy will be assessed over Day 2 through Day 5 following treatment, in addition to the primary efficacy measure of complete response during the 24-hour period after the start of chemotherapy. The most frequent adverse events associated with palonosetron are similar to those seen with other 5-HT3 antagonists and include headache and constipation.

Under the terms of the exclusive license agreement, MGI PHARMA will make $11 million in upfront payments, already including the initial $5 million made upon signature of the letter of intent, and will make additional payments based on the achievement of certain milestones through the approval of palonosetron in the U.S. Helsinn will continue to fund and conduct all development of palonosetron. MGI PHARMA will also pay royalties and product supply fees based upon net sales. Helsinn will supply finished product ready for distribution, the active ingredient of which is manufactured at Helsinn's new state-of-the-art facility (Helsinn Advanced Synthesis SA) dedicated to the production of high potency active ingredients.

About MGI PHARMA

MGI PHARMA, INC. is an oncology-focused pharmaceutical company that acquires, develops and commercializes proprietary products that meet patient needs and build shareholder value. MGI

focuses its sales efforts solely in the United States and collaborates with other pharmaceutical or biotechnology companies for its products in international markets. For more information about MGI, please visit the Company's web site at www.mgipharma.com.

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About HELSINN HEALTHCARE SA

Helsinn (www.helsinn.com) is a privately owned pharmaceutical group with headquarters in Switzerland. Helsinn's core business is licensing. The company's business strategy is to in-license new chemical entities at a certain stage of development. Helsinn completes the development by performing pre-clinical and clinical studies as well as chemical and pharmaceutical development through the attainment of market approval in strategic markets (USA and Europe). The finished products and active pharmaceutical ingredients are manufactured at Helsinn and supplied to its marketing partners for distribution.

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safe and effective in humans and to ultimately compete successfully with other therapies, development or acquisition of additional products, continued sales of MGI PHARMA's marketed products, reliance on contract manufacturing, changes in strategic alliances, and other risks and uncertainties detailed from time to time in the company's filings with the Securities and Exchange Commission, MGI PHARMA does not intend to update any of the forward-looking statements after the date of this news release to conform them to actual results.

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NEWS RELEASE

FOR IMMEDIATE RELEASE
April 12. 2001

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MGI PHARMA INITIATES ADDITIONAL PHASE 2 TRIAL OF IROFULVEN IN HORMONE-REFRACTORY PROSTATE CANCER

Phase 2 Trial to Evaluate Every-Other-Week Dosing Schedule

MINNEAPOLIS, April 12, 2001 – MGI PHARMA. INC., (Nasdaq: MOGN) today announced that it has initiated an additional phase 2 clinical trial of irofulven, its novel anti-cancer compound, using an intermittent dosing schedule to treat hormone-refractory, prostate cancer patients. This randomized, multi-center Phase 2 trial conducted in Europe will evaluate the anti-tumor activity, safety, and clinical benefit of irofulven as a single agent and in combination with prednisone. Up to 54 patients will be treated with irofulven on an every-other-week dosing schedule. Results from this Phase I trial will be used to develop recommendations for an anticipated Phase 3 trial with irofulven in prostate cancer. Decrease in PSA (prostate-specific antigen) is the primary endpoint, along with objective tumor response in patients with measurable disease. Time to disease progression, duration of response, overall survival and clinical benefit will also be assessed. The patient enrollment period for this Phase 2 trial is expected to last approximately 18 months.

The anti-tumor activity of irofulven in hormone-refractory prostate Cancer patients has already been evaluated in a prior Phase 2 trial where irofulven was dosed daily for five days every 28 days. All of the 32 patients who were evaluable for PSA response had stable or decreasing PSA levels and four of those patients had partial PSA responses (defined as a decrease of at least 50 percent for at least one month).

In addition, one of the nine patients who had measurable disease had an objective partial response.

Improved tolerance and an ability to deliver more drug over multiple courses of treatment has been observed in an ongoing dose-optimization trial using an every-other-week dosing schedule, which will be assessed in this new trial. This new multi-center Phase 2 trial of irofulven, in patients with hormone-refractory prostate cancer, used alone or in combination with prednisone, will provide us with valuable additional insight about irofulven's role in treating this type of cancer," said Professor Stephane Culine, head of the medical oncology department of Val d'Aurelle-Paul Lamarque Anticancer Center at Montpellier in France. And the lead Investigator for the trial. "Considering the anti-tumor activity shown in a previous Phase 2 trial and a new dosing schedule that is better tolerated, we hope to demonstrate further evidence of irofulven's efficacy in this disease."

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Dr. John MacDonald, senior vice president of research and development at MGI PHARMA commented, "Our continued research in this area demonstrates MGI's commitment to addressing the unmet needs of cancer patients, and hormone-refractory prostate cancer is clearly an area where we hope irofulven will make a difference in patients' lives."

About Hormone-Refractory Prostate Cancer

In men, carcinoma of the prostate is the second highest cause of cancer-related death after lung cancer, with an estimated 198,100 new cases to be diagnosed and 31,500 anticipated deaths in the United States in 2001, according to the American cancer society. Worldwide, the incidence of microscopic prostate malignancy increases from 30 percent in men over 50 years in age, to more than 50 percent in men in their eighties. The standard treatment for local disease is either radical prostatectomy or pelvic irradiation. Approximately 20 to 30 percent of men with prostate cancer have distant metastases at the time of diagnosis.

Hormone therapy is the first therapy to show efficacy in reducing tumor growth, but the duration of the response averages only 12 to 18 months. Among patients with disseminated disease, 70 to 80 percent experience subjective symptomatic relief, and approximately 40 to 50 percent achieve objective remission. Second-line hormonal therapy provides clinical improvement in only 10 to 20 percent of such patients, has a duration of less than six months, and does not significantly improve survival, indicating that a large number of patients become hormone-refractory after first-line treatment. Chemotherapy has been of limited value in the management of patients who have become refractory to hormone therapy. Despite many years of effort to develop effective chemotherapy administered before, during, or after hormone therapy, few effective drugs have been identified.

Advanced clinical trials are needed to compare the current standard treatment of mitoxantrone in combination with prednisone to other drug combinations to

identify the best combination for improving quality of life and positively affecting survival.

About Irofulven

Irofulven (also known as MGI 114, hydroxymethylacylfulvene, or HMAF) is the first product candidate being developed by MGI PHARMA from its family of proprietary anti-cancer compounds called acylfulvenes. Irofulven is currently being tested in a series of clinical trials for the treatment of solid tumors, across a variety of cancers. Irofulven has demonstrated promising anti-tumor activity as a single agent in clinical testing against pancreatic, ovarian and prostate cancers. In February 2001, MGI PHARMA initiated a pivotal Phase 3 trial of irofulven in advanced-stage, gencitabine-refractory pancreatic cancer patients. Side effects from irofulven are comparable to those seen with marketed chemotherapies and include bone marrow suppression (decreases in platelets or white blood cell counts), nausea, vomiting and fatigue. Patients and health care providers seeking information on the various irofulven clinical trials may call MGI PHARMA Medical communications Help Line at 1-800-562-5580 or the National Cancer Institute's cancer Information Service at 1-800-4-CANCER (TTY 1-800-332-8515).

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Exhibit 99.7

[MGI LOGO]

NEWS RELEASE

FOR IMMEDIATE RELEASE
April 18, 2001

CONTACT:
Maggie P. Knack
Director. Investor Relations
952-346-4771
IR@mgipharma.com

MGI PHARMA REPORTS 2001 FIRST QUARTER RESULTS

Company Portfolio Now Includes Three Key Marketed Products & Two Phase 3 Compounds: Reports Record Salagen(R) Tablets Sales

MINNEAPOLIS, April 18, 2001 – MGI PHARMA, INC., (Nasdaq: MOGN) today reported that product sales revenue increased 53 percent to $7.0 million: in the first quarter ended March 31. 2001, from 54.6 million in the first quarter of 2000. Total revenues increased 46 percent to $7.6 million in the 2001 first quarter from $5.2 million in the first quarter a year ago, total costs and expenses increased 98 Percent to $11.1 million in the 2001 first quarter from $5.6 million in the 2000 first quarter. The Company reported a net loss of $3.1 million, or $0.19 per share, in the first quarter of 2001 compared to a net loss of $9.5 million, or $0.63 per diluted share, in the first

quarter of 2000. As previously noted, the prior year's results have been restated for the effect of implementing Staff Accounting Bulletin 101 as of January 1, 2000 and resulted in in charge of $9.4 million, or $0.62 per share, it the first quarter of 2000.

The quarter's strong performance in product sales revenue was primarily due to growth in sales of Salagen(R) Tablets (pilocarpine hydrochloride) and from two recent oncology product additions, Hexalen(R) capsules (altretamine) and Mylocel(TM) Tablets (hydroxyurea). The increase in costs and expenses was primarily due to an increase in research and development expense related to the expanded development of two product candidates, irofulven and MG98, the recent promotional launches of new products, and an increase in selling expenses for the expansion of the sales organization which principally occurred in the second quarter of 2000.

"We continue to deliver on our business plan by expanding our marketed product portfolio and accelerating our clinical development programs for irofulven and MG98," said Chuck Blitzer, president and CEO of MGI PHARMA. "At the same time, our experienced marketing team and oncology sales force is delivering a record quarter performance in product sales. The first quarter of 2001 includes sales from both Hexalen capsules and Mylocel Tablets, for which we began direct promotion in March, in addition to the steadfast sales performance of Salagen Tablets, our flagship commercial product. MGI is making great strides toward our goal of becoming a leader in oncology."

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Recent Company Highlights

Clinical Developments:

- Initiated a pivotal Phase 3 clinical trial of irofulven, its novel anti-cancer compound, for patients with advanced-stage pancreatic cancer. The trial is a randomized, multi-center, international trial in advanced-stage pancreatic cancer patients whose disease progressed after treatment with gemcitabine, the current standard-of-care treatment.
- Initiated a Phase 2 clinical trial of irofulven for patients with refractory or recurrent advanced ovarian cancer.
- Initiated another Phase 2 clinical trial of irofulven to treat hormone-refractory prostate cancer patients. This randomized, multi-center Phase 2 trial conducted in Europe will evaluate the anti-tumor activity, safety, and clinical benefit of irofulven as a single agent and in combination with prednisone.
- Made six poster presentations on irofulven's anti-tumor activity and mechanism of action at this year's American Association for Cancer Research (AACA) meeting held in March. The preclinical data presented serves as the basis for MGI's plans to expand the clinical development of irofulven in a variety of cancers both as a single agent and in combination with other drugs.

In-licensed Products:

- Signed definitive agreement granting MGI PHARMA exclusive North American license and distribution rights to palonosetron, a potent and selective 5-HT3 antagonist with an extended half-life, in Phase 3 development for the prevention of chemotherapy-induced nausea and waiting (CINV) with Helsinn Healthcare SA. When launched, palonosetron would compete in the $1 billion North American CINV market. In addition to the previously disclosed $11 million in upfront payments that became due upon signing the definitive agreements. MGI PHARMA is obligated to pay a total of $27 million in milestone payments upon achievement of the underlying development objectives, including marketing approval of palonosetron in the United States. Helsinn will continue to fond and conduct all development of palonosetron.

- Signed exclusive agreement for the U.S. marketing and distribution rights for Mylocel tablets, a recently FDA-approved oral tablet formulation of hydroxyurea for the treatment of certain malignancies, with Barr Laboratories, Inc.

- Launched exclusive promotion of Hexalen Capsules (altretamine) and Mylocel Tablets (hydroxyurea) in the U.S. oncology market.

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2001 Financial Outlook

This section provides forward-looking information about MGI PHARMA's financial outlook for 2001. These projections include the impact of MGI PHARMA's entire product portfolio, which comprises Salagen(R) Tablets, Hexalen(R) capsules. Mylocel(TM) Tablets, irofulven and the other acylfulvenes, palonosetron, MG98 and the complementary small molecule inhibitor program. The disclosure notice paragraph regarding forward-looking statements at the end of this news release to especially applicable to this section. For the year ending December 31, 2001:

- Product sales are currently projected to grow 15 to 20 percent. (increased from last quarter guidance)
- Cost of product sales as a percent of sales revenue is expected to range from 10 to 15 percent,
- Licensing revenue is expected to approximate the annual 2000 amount after application of SAB 101, and would increase if commercial rights for irofulven outside the United States are out-licensed.
- R&D expense is expected to range from $35 to $45 million depending on the pace of irofulven and MG98 development and the timing of palonosetron milestone achievements.
- Selling, general and administrative expenses are expected to be approximately $25 million or less, (decreased from last quarter guidance)

- Amortization expense related to the acquisition of Hexalen Capsules is expected to be approximately $1.2 million, and
- Net loss is expected to range from $35 to $45 million.

Webcast of First Quarter Conference Call

MGI PHARMA will broadcast ins 2001 first quarter results in an investor conference call live over the Internet on Wednesday, April 18, 2001 at 1:00 p.m. Eastern Time. The company's executive management team will review first quarter 2001 financial results, answer questions from analysts and investors, and provide commentary on MGI's product portfolio and business outlook. All interested parties are welcome to log on to www.mgipharma.com to listen to the webcast, which will also be archived on the company's web site.

About MGI PHARMA

MGI PHARMA, INC. is an oncology-focused pharmaceutical company that acquires, develops and commercializes proprietary products that meet patient needs and build shareholder value. MGI focuses its sales efforts solely in the United States and collaborates with other pharmaceutical or biotechnology companies for its products in international markets. For more information about MGI please visit the company's web site at www.mgipharma.com.

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This news release contains forward-looking statements that may include statements regarding intent, belief or current expectations of the Company and its management. These forward-looking statements are not guarantees of future performance and involve a number of risks and uncertainties that may cause the company's actual results to differ materially from the results discussed in these statements. Factors that might affect MGI PHARMA's results include, but are not limited to the ability of MGI PHARMA's product candidates to be proven safe and effective in humans and to ultimately compete successfully with other therapies, continued sales of MGI PHARMA's commercial products, development or acquisition of additional products, reliance on contract manufacturing, changes in strategic alliances, continued access to capital, and other risks and uncertainties detailed from time to time in the company's filings with the Securities and Exchange Commission. MGI PHARMA does not intend to update any of the forward-looking statements after the date of this news release to conform them to actual results.

(more)

MGI PHARMA, INC.
Statements of Operations
(Unaudited)

	Three Months Ended March 31.	
	2000	2001
Revenues:		
Sales	$4,566,295	$6,984,108
Promotion	250,000	0
Licensing	361,056	591,669
	5,177,351	7,575,777
Costs and Expenses:		
Cost of sales	304,071	789,353
Selling, general and administrative	3,520,584	6,492,775
Research and development	1,804,218	3,553,818
Amortization	0	295,494
	5,628,873	11,131,440
Loss before interest and taxes	(451,522)	(3,55,663)
Interest income	372,846	436,166
Loss before taxes	(78,676)	(3,119,497)
Provision for income taxes	61,279	0
Loss before cumulative effect of change principle	(139,955)	(3,119,497)

Cumulative effect of change is accounting principle	(9,402,643)	0
Net loss	$(9,542,598)	$(3,119,497)
Net loss per common share:		
Basic		
Loss before effect of accounting change	$(0.01)	$(0.19)
Cumulative effect of accounting change	(0.62)	0.00
Net loss	$(0.63)	$(0.19)
Assuming dilution		
Loss before effect of accounting change	$(0.01)	$(0.19)
Cumulative effect of accounting change	(0.62)	0.00
Net loss	$(0.63)	(0.29)
Weighted average number of common shares:		
Basic	15,217,199	16,532,670
Assuming dilution	15,217,199	16,532,670

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Balance Sheet Data
(unaudited)

	December 31, 2000	March 31, 2001
Cash and short term investments	$29,898,787	$23,864,961
Total assets	52,743,570	48,612,974
Total stockholders' equity	26,045,617	23,918,230

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NEWS RELEASE

FOR IMMEDIATE RELEASE
April 25, 2001

CONTACT:
Maggie P. Knack
Director, Investor Relations
952-346-4771
IR@mgipharma.com

MGI PHARMA AMNOUNCES ISSUANCE OF KEY PATENT FOR INHIBITION OF DNA METHYLTRANSFERASE

MINNEAPOLIS, April 25, 2001 MGI PHARMA, INC., (Nasdaq: MOGN) today announced that a key patent for "Inhibition of DNA methyltransferase" was recently granted to MethylGene Inc., its partner with whom the Company has an exclusive North American license, research and development agreement for inhibitors of DNA methyltransferase. As part of its existing agreement with MethylGene, MGl PHARMA has the exclusive license to develop, market and sell in North America MG98, a second-generation mRNA inhibitor, and any small molecule inhibitor of DNA methyltransferase derived from the two companies' research collaborations. This new patent provides significant expansion of the intellectual property rights available under this exclusive agreement.

U.S. Patent No. 6,184,211 is entitled "Inhibition of DNA Methyltransferase" and covers the administration of an agent that could allow the human body to restore normally occurring mechanisms to slow or stop the growth of cancerous tumors. DNA methyltransferase is an enzyme that inhibits the expression of genes that would otherwise slow or stop tumor growth. When DNA methyltransferase is over-expressed end hypermethylation occurs, tumor suppressor genes may be "turned off." Hypermethylation, in conjunction with cancerous conditions, can allow cancer cells to proliferate. Hypermethylation of tumor suppressor genes has been observed to occur in a wide variety of human cancers. Recent findings also suggest that the extent of tumor suppressor gene methylation correlates with disease progression for a variety of tumor types. In addition, it appears this enzyme also affects

the expression of other key genes involved in cancer progression, Such as DNA repair genes and hormone receptors.

"The role of DNA methylation in the causation and progression of human cancer is an area of very active recent research. Our research with MethylGene has demonstrated that selective inhibition of DNA methyltransferase results in tumor growth inhibition or tumor regression," notes Lonnie Moulder, executive vice president of MGI PHARMA. "Targeting the re-expression of silenced tumor suppressor genes at the molecular level is considered one of the most exciting new approaches for cancer therapeutics. This new patent will provide important intellectual property protection for our work in this field."

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MGI PHARMA is developing MG98 for the purpose of blocking production or the nuclear enzyme DNA methyltransferase. Preventing DNA methyltransferase production allows tumor suppressor genes that have been silenced by methylation, to be re-activated. MG98 has already demonstrated anti-cancer activity in Phase 1 trials. MGI also initiated a Phase 2 trial of MG98 in head and neck cancer patients, and intends to further evaluate MG98 in other cancers where silencing of tumor suppressor genes by DNA methyltransferase has been documented. In preclinical models, MG98 used alone and in combination with other anti-cancer agents has caused shrinkage or inhibited growth of human tumors.

Along with MG98, MGI PHARMA licensed a complementary small molecule DNA methyltransferase inhibitor program that shares the same goal of preventing methylation and silencing tumor suppressor genes. However, the small molecules are being screened for their potential no bind to DNA methyltransferase and block its activity, rather than prevent its production.

The inventor of this patent is Dr. Moshe Szyf, assistant professor of Pharmacology and Therapeutics at McGill university. MethylGene is the exclusive. worldwide assignee of the patent.

About MethylGene

MethylGene Inc. is a privately held, Canadian biopharmaceutical and chemistry-driven rational drug design company focused on the inhibition of enzyme targets associated with disease. MethylGene combines functional genomic technologies with the application of mechanism-based small molecules and mRNA inhibitors to discover, patent, develop and commercialize novel therapeutics for cancer and infectious disease. MethylGene's lead compound, MG98, which is partnered for North America with MGI PHARMA, is currently in Phase 2 clinical trials. The Company has other research and development programs to develop small molecule inhibitors of DNA methyltransferases, histone deacetylases, beta-lactamases and other enzyme targets.

About MGI PHARMA

MGI PHARMA, INC. is an oncology-focused pharmaceutical company that acquires, develops and commercializes proprietary products that meet patient needs and build shareholder value. MGI focuses its sales efforts solely in the United States and

collaborates with other pharmaceutical or biotechnology companies for its products in international markets. For more information about MGI, please visit the company's web site at www.mgipharma.com.

This news release contains forward-looking statements that may include statements regarding intent, belief or current expectations of the Company and its management. These forward-looking statements are not guarantees of future performance and involve a number of risks and uncertainties that may cause the Company's actual results to differ materially from the results discussed in these statements. Factors that might affect MGI PHARMA's results include, but are not limited to the ability of MGI PHARMA's product candidates to be proven safe and effective in humans and to ultimately compete successfully with

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other therapies, continued sales of MGI PHARMA's marketed products, development or acquisition of additional products, reliance on contract manufacturing, changes in strategic alliances, continued access to capital and other risks and uncertainties detailed from time to time in the company's filings with the Securities and Exchange Commission. MGI PHARMA does not intend to update any of the forward-looking statements after the date of this news release to conform then to actual results.

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END PRIVACY ENHANCED MESSAGE

HELSINN

October 3rd, 2001

HELSINN HEALTHCARE ANNOUNCE THE COMPLETION OF PATIENT ENROLLMENT FOR FIRST PALONOSETRON PHASE 3 PIVOTAL TRIAL

HELSINN HEALTHCARE SA announced the completion of patient enrollment for the first of the pivotal Phase 3 trials of palenosetron, a novel 5-HT, antagonist. Palonosetron is a potent, highly selective 5-HT, antagonist with an extended half-fife, currently In Phase 3 development in the United States and Europe for the prevention of chemotherapy-induced nausea and vomiting (CINV). HELSINN expects to complete patient enrollment for the remaining trials in the Phase 3 program near the end of 2001 and plans to submit a New Drug Application (NDA) in the U.S. and Europe in the first half of 2002.

The double-blinded, randomized Phase 3 clinical trial program aims to compare intravenous (IV) palonosetron to currently marketed 5-HT, antagonists arid is being conducted at medical centers across North America and Europe. It is expected that over 1,800 cancer patients receiving either highly- or moderately emetogenic chemotherapy will be enrolled in the trials. Based on the extended half-life of patonosetron and the results of a Phase 2 trial, its efficacy is being assessed over Day 2 through Day 5 following treatment, in addition to the primary efficacy measure of complete response during the 24-hour period after the start of chemotherapy.

Results of Phase 1 trials in healthy volunteers to assess the pharmacokinetic properties and safety of palonosetron were presented at this year's American

Society of Clinical Oncologists (ASCO) meeting in May 2001. Palonosetron was found to have a plasma elimination half-life of 37 hours, which is at least three times longer than marketed agents in its class. This extended half-life of palonosetron and the results of Phase 2 trials assessing the efficacy beyond 24 hours differentiate palonosetron from the currently marketed 5-HT, antagonists indicated for CINV.

Having been studied in more than 1,000 subjects In Phase 1 and Phase 2 trials. palonosetron was well tolerated and had no unexpected or serious adverse reactions. The most frequent adverse events associated with palonosetron are similar to those seen with other 5-HT, antagonists and include headache and constipation, which are generally mild to moderate.

CINV is estimated to occur in approximately 85 percent of cancer patients undergoing chemotherapy and can result in delay or even discontinuation of treatment The advent of 5-HT, antagonists has revolutionized the management of nausea and vomiting experienced by cancer patients undergoing chemotherapy.

HELSINN is the worldwide licensor of palonosetron and is conducting the Phase 3 trials of palonosetron that will form the basis for its registration in the United States. In April of this year, MGI PHARMA, an oncology-focused pharmaceutical company based in Minneapolis, and HELSINN signed an agreement granting MG% the exclusive U.S. and Canadian licensing and distribution rights to palonosetron. Once approved, palonosetron will compete in the CINV treatment market, which is rapidly approaching $1 billion in North America.

HELSINN's negotiations with potential European licensing partners are ongoing, and out-licensing activities for remaining markets will commence next year.

HELSINN

January 16, 2002

HELSINN & MGI PHARMA ANNOUNCE COMPLETION OF PIVOTAL PHASE 3 TRIALS OF PALONOSETRON

LUGANO, SWITZERLAND, and MINNEAPOLIS USA January 16, 2002 – HELSINN HEALTHCARE SA, a privately owned Swiss pharmaceutical group, and MGI PHARMA, INC., (Nasdaq: MOGN) an oncology-focused pharmaceutical company based in Minneapolis, today announced that patient treatment is completed and the data analysis is underway for the pivotal Phase 3 trials of their investigational agent. Palonosetron. Palonosetron is a potent, highly selective 5-HT, receptor antagonist in development in North America and Europe for the prevention of chemotherapy-induced nausea and vomiting (CINV). Submission of the New Drug Application (NDA) for Palonosetron is now planned to occur in the third quarter of 2002.

The Phase 3 clinical trial program was initiated in April 2000 and was designed to compare intravenous (IV) Palonosetron to currently marketed 5-HT, antagonists. The trials were conducted at more than 130 medical centers across North America and Europe, with more than 1,800 cancer patients receiving either highly- or moderately-emetogenic chemotherapy. Based on the extended half-life of Palonosetron and the results of a Phase 2 trial, the efficacy of Palonosetron in the Phase 3 trial is being assessed over Day 2 through Day 5 following treatment, in addition to the primary efficacy measure of complete response during the 24-hour period after the start of chemotherapy.

"We are pleased to have completed all patient treatment and to have begun analysis of the data collected in the Palonosetron Phase 3 clinical program," said Luigi Baroni, senior director of Scientific Affairs Division at HELSINN. "The Phase 2 clinical trial results were promising, and we are hopeful that the Phase 3 Palonosetron data will demonstrate that it can make a difference for cancer patients suffering from CINV."

The half-life of other available 5-HT, receptor antagonists ranges from approximately five to nine hours, whereas Palonosetron has a plasma elimination half-life of nearly 40 hours," notes Dr. John MacDonald, senior vice president of Research and Development at MGI. "The activity seen with Palonosetron in the Phase 2 trial, coupled with its safety profile observed to date, led to the initiation of a Phase 3 program to assess the ability of the drug to provide prolonged protection against CINV with a single dose."

August Consulting

515 Capital of Texas Highway
Suite 150
Austin, Texas 78746
Tel: 512.347.1755
Fax: 512.347.9375

February 7, 2002

Dr. Victor Razckowski, MD, Acting Director

Division of Gastrointestinal and Coagulation Drug Products

HFD-180

Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Palonosetron HCl IND 39,797 Amendment #140
Request for Pre-NDA Meeting
Sponsor: Helsinn Healthcare SA

Dear Dr. Razckowski:

In accordance with 21 CFR, 312.47 (b) (2), a pre-NDA meeting is requested in preparation for the palonosetron NDA. All phase 3 efficacy trials - PALO-99-03 and PALO-99-04 involving moderately emelogenic CINV and PALO-99-05 involving highly emelogenic CINV - have completed enrollment and preliminary efficacy data are available.

Consistent with your letter of October 10, 2001, please find attached at Appendix #1 preliminary efficacy data for PALO-99-03. In this study, the preliminary data for Complete Response, which is the primary efficacy outcome measure for acute CINV, was 81.0% (153/189) for palonosetron 0.25 mg,

73.5% (139/189) for palonosetron 0.75 mg, and 68.6% (127/185) for ondausetron 32 mg, Preliminary efficacy results for PALO-99- 04 will he included in the background information package projected to be submitted four weeks prior to the meeting, and preliminary efficacy data for PALO-99-05 will be presented at the meeting.

The following information is provided to you regarding the requested meeting:

1. Product name and application number: Palonosetron HCI Intravenous Injection, 0.25 mg (0.05 mg/mL), or 0.75 mg (0.15 mg/mL). Please note that one of these product strengths will be selected for marketing approval based on the phase 3 efficacy data. The NDA number is 21-372.

2. Proposed Indication: "Palonosetron HCI is indicated for the prevention of nausea and vomiting associated with initial and repeated courses of emetogenic cancer chemotherapy, including highly emetogenic chemotherapy."

3. Type of meeting requested: Type B.

4. Brief statement of the purpose of the meeting: The purpose of the meeting is to uncover any unresolved problems regarding overall programs supporting the planned NDA, to review and discuss the planned ISS and ISE analysis and the planned format and content of the ISS and ISE, to discuss the status of the pediatric safety and effectiveness trial and plans to submit these data to review and discuss the proposed labeling, to discuss the proposed approach to the presentation and formatting of data in the NDA and to discuss administrative matters associated with the planned NDA.

5. List of specific objectives/outcomes expected from the meeting.

a. Reach agreement with FDA regarding the typo of NDA submission: 505b1 submitted in hard copy in traditional format (non CID) with CRTs and possibly CRFs submitted electronically on CD.

b. Present PALO-99-05 preliminary efficacy results, review preliminary results for all pivotal clinical efficacy trials and reach agreement on any matters identified by FDA.

c. Review proposed ISS and ISE information to be submitted in the background package and reach agreement on the content and format of the ISS and ISE

d. Discuss the pediatric clinical safety, efficacy and pharmacokinetic study to be submitted, discuss the regulatory approach and schedule to submit these data, and obtain FDA's feedback regarding the acceptability of this approach.

e. Review and discuss the pharrn/tox program, in particular the carcinogenicity and preclinical cardiovascular safety data, and obtain FDA's feedback regarding these data for the planned NDA. f. Briefly

f. Review the biopharm program planned for the NDA and address any outstanding matters identified by FDA.

g. Briefly review the CMC program and address any outstanding matters identified by FDA.

h. Review proposed draft labeling and obtain FDA's feedback.

i. Review proposed content and format for the NDA and obtain FDA's feedback.

j. Review administrative items planned for the NDA.

k. Present and discuss the planned NDA submission schedule.

6. Preliminary proposed agenda and specific questions for purposes of supporting an NDA submission for Palonosetron HCI for Injection.

a. Introductions, including a request for FDA minutes and list of meeting attendees. (5 minutes)

b. Discussion of the proposed NDA submission route and nature of the submission. Please advise us if you agree with the proposed type of NDA submission: 505b1 submitted in hard copy in traditional format (non CTD) with CRTs and possibly CRFs submitted electronically on CD, and discuss as needed. Please advise us of any electronic data you wish to be submitted in the NDA. (5 minutes)

c. Presentation of preliminary PALO-99-05 phase 3 pivotal efficacy results and overall preliminary efficacy results for all phase 3 pivotal efficacy trials. Please advise us of the acceptability of these preliminary pivotal efficacy data for purposes of NDA submission, comment and discuss as needed. (30 minutes)

d. Discussion of the ISS and LSE. Information regarding the ISS and ISE analyses will be provided in the background pre-meeting document. Please advise us of the acceptability of the proposed content and format of the planned ISS and ISE, comment and discuss as needed. (30 minutes)

e. Discussion of plans to submit the PALO-99-07 pediatric clinical trial. A proposed plan to submit a pediatric assessment for the NDA based on pediatric

safety, efficacy and pharmacokinetic study PALO-99-07 will be included in the background package. PALO-99-07 is not projected to be completed until after NDA submission. Please advise us if you agree with the proposed plan to submit the pediatric clinical study, comment and discuss as needed. (5 minutes)

f. Discussion of the pharm/tox program. A brief tabular summary of key studies in the pharm/tox program arid status will be presented in the background package. Please advise us regarding the acceptability of the overall program for purposes of NDA submission, provide commentary and discuss as needed. (30 minutes)

g. Discussion of the CMC program. A brief overview of the CMC program, consistent with the CMC program presented and agreed upon at the FDA meeting held January 31, 2002, will be provided in the background package. Please advise us if you agree with the CMC program for purposes of the planned NDA submission, provide commentary and discuss as needed. (10 minutes)

h. Discussion of the biopharm program. A brief tabular overview of the biopharm program and status will be included in the background package. Please advise us if you agree with the program for purposes of the planned NDA submission, comment and discuss as needed. (10 minutes).

i. Discussion of draft labeling. Proposed draft labeling will be included in the background package. Please advise us if you agree with the proposed draft labeling for purposes of the planned NDA submission, comment and discuss as needed. (25 minutes)

j. Discussion of the content and format of the NDA. The proposed NDA index, outlining sections and

subsections to be included in the NDA, will be provided in the background package. Please advise us if you agree with the proposed content and format for the NDA, comment and discuss as needed. (15 minutes)

k. Discussion of administrative items in the NDA. Please review the proposed NDA index to be included in the background package and advise us if you agree with the proposed administrative items planned for inclusion in the NDA such as user's fee forms, debarment certification, financial information, field copy certification, etc., - we do not wish to miss anything - and discuss as needed. (10 minutes)

l. Discussion of the NDA submission schedule. Please comment and discuss as needed regarding the proposed NDA submission schedule. (2 minutes)

m. Summary comments by the FDA Division Acting Director, Dr. Raczkowski. (3 minutes)

n. Meeting adjourns.

7. Planned Sponsor's attendees:

a. Dr. Dario Ceriani, Senior Manager Regulatory Affairs, Helsinn.

b. Dr. Luigi, Baroni, Direclor of Scientific Affairs, Helsinn.

c. Dr. Giorgio Calderari, Chief Manufacturing Officer , Helsinn. Dr. Claudio Berettera, Project Leader, Helsinn.

e. Dr. Alberto Macciocchi, Deputy Director, Clinical Affairs, Helsinn.

f. Dr. Cecilia Moresino, Statistician, Helsinn.

g. Dr. Sergio Cantoreggi, Manager, Preclinical Development, Helsinn.

h. Dr. Simona Parisi, Manager, Product Development. Helsinn.

i. Dr. Kristen Pluharty, Clinical Pharmacology Consultant.

j. Dr. Mike Thom, Biostatistics Consultant

k. Dr. Steven Grunberg, Clinical Oncology Consultant.

l. Ms. Susan Skinner, CMC Consultant.

m. Dr. Robert Wolters, CMC Consultant

n. Dr. Craig Lehmann, Regulatory Consultant.

8. Requested FDA attendees:

a. Dr. Raczkowski, Acting Director, DGCDP.

b. Dr. Gallo-Tones, Medical Team Leader, DGCDP.

c. Dr. Robert Prizont, Medical Officer, DGCDP.

d. Dr. Tom Permutt, Statistics Team Leader, DGCDP.

e. Mr. Ed Nevius, Supervisor, Mathematical Statistics, DOBII.

f. Dr. Jasti Choudary, Pharm/Tox Team Leader, DOCDP.

g. Dr. Yash Chopra, Pharmacology Reviewer, DGCDP.

h. Dr. Liang Zhou, Chemistry Team Leader, DGCDP.

i. Dr. Joe Sieczkowski. Chemistry Reviewer, DGCDP.

j. Dr. Saresh Doddapaneni, Senior Staff Fellow, Biopharrn,DPEII.

k. Mr. Brian Strongin, Regulatory Health Project Manager, DGCDP.

9. Information Package Submission Date. It is projected that the information package including agenda and final specific questions will be submitted four weeks prior to the scheduled date for the Pre-NDA meeting.

10. Suggested Dates and Times for the Pre-NDA Meeting: The week April 8th to April 12th, 2002, in the morning or afternoon is proposed for the meeting. We request a 3-hour meeting.

I will call Mr. Brian Strongin of your Division for purposes of arranging the meeting. Please call me at 512-347-1755, fax 512-347-9375, if you wish further information.

Best Regards,

/s/ Craig Lehmann
Craig Lehmann, Pharm.D.
Authorized Representative for the IND

Submitted: original plus two copies

Appendix #1 — Preliminary efficacy data for pivotal phase 3 efficacy trial PALO-99-03

Cy: Dr. Dario Ceriani, Senior Manager Regulatory Affairs (Helsinn Healthcare SA)

Mr. Franco DeVecchi Sr., Authorized US Corporate Representative (VPCI Inc.)

AMENDMENT No.1
TO THE SUPPLY AND PURCHASE AGREEMENT

This Amendment No. 1 ("Amendment") to the License Agreement is made and effective as of this 16 day of November, 2003 between HELSINN BIREX PHARMACEUTICALS Ltd., a corporation organized and existing under the laws of Ireland and having its registered office at Damastown, Mulhuddart, Dublin 15, Republic of Ireland (hereinafter called "HBP"), of the one part, and MGI PHARMA, INC., a corporation organized and existing under the law of the state of Minnesota, United States of America and having its registered office at 5775 West Old Shakopee Road, Suite 100, Bloomington, MN 55437-3174, USA (hereinafter called "MGI") of the other part.

WHEREAS, MGI and HBP's Affiliate Helsinn Healthcare SA ("HHC") entered on 6 April 2001 into a License Agreement granting MGI an exclusive, royalty-bearing license under the Patents and to use the Know-how, to distribute, promote, market and sell the Products in the Territory;

WHEREAS, HBP and MGI entered on 6 April 2001 into a Supply and Purchase Agreement (hereinafter referred to as "Agreement") relevant to the supply of the Products from HBP to MGI;

WHEREAS, as a result of Amendment No. 2 to the License Agreement, entered into between MGI and HHC on November 14, 2003 it is now necessary to update and amend the Agreement as described below;

WHEREAS, all capitalized terms used herein shall have the same meaning as set forth in the Agreement unless otherwise indicated.

NOW, THEREFORE, in consideration of the mutual covenants and conditions hereinafter set forth, the Parties agree as follows:

1. With effect from the date hereof, the definition of "Products" included in Article 1.9 of the Agreement shall be entirely replaced by the following new definition:

   "1.12 "Products" means the pharmaceutical preparations for human use (i) in IV dosage form for use in CINV. (ii) in IV dosage form for use in PONV. (iii) in oral dosage form, containing the Compound as an active ingredient in the formulations described in one or more Registrations and such other formulations or uses for which MGI exercises its right of first refusal pursuant to Article 2.6 of the License Agreement. The IV formulation of the Product for CINV, as approved by the U.S. Food and Drug Administration as NDA 21-372 and submitted to the Therapeutic Products Programme of Canada in the IND 9427-H0836-21C, is described in the First Appendix hereto."

2. The floor price of USD 28.50 (US Dollars twenty-eight and fifty cents) per vial, indicated in paragraph 1 of the Second Appendix to the Agreement, shall have to be interpreted and construed as referring exclusively to the IV dosage form (per vial) and oral dosage form (per tablet) for CINV. The floor price per vial for the IV dosage form for PONV destined for the market of the United States of America shall be USD 8.20 (US Dollars eight and twenty cents).

3. Subject to paragraph 2 above, any and all provisions of paragraphs 1, 2 and 3 of the Second Appendix to the Agreement, including but not limited to the supply of free goods provided at paragraph 3 of said Appendix, shall be fully applicable also with regard to each of the IV dosage form for PONV and to the oral form of the Products.

4. Upon execution of this Amendment, the Agreement shall be applicable, mutatis mutandis, also to the IV dosage form for PONV and to the oral dosage form of the Products, except as otherwise expressly provided or limited through specific provisions in this Amendment.

5. MGI's address for the purposes of notices under this Amendment and the Agreement shall be as set forth above.

6. In the case of any conflict between this Amendment and the Agreement, the terms of this Amendment shall prevail. Except as amended hereby, the Agreement shall continue in full force and effect.

IN WITNESS WHEREOF, the Parties hereto have causes this Amendment to be executed in duplicate by their duly authorized officers.

For and on behalf of
HELSINN BIREX PHARMACEUTICALS Ltd.

/s/_____
Enrico Braglia
Managing Director

/s/_____
Riccardo Braglia
Managing Director

For and on behalf of
MGI PHARMA INC.

/s/ Leon O. Moulder Jr.
Leon O. Moulder Jr.
President & CEO

/s/ William C. Brown
William C. Brown
Executive Vice President & CFO

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

CALDERARI, ET AL.

Filing Date: July 21, 2005

Art Unit: 1614

Serial No.: 11/186,311

Examiner: Gembeh, Shirley V.

Title: LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

STATUTORY DECLARATION OF GIORGIO CALDERARI, DANIELE BONADEO, ROBERTA CANNELLA, ENRICO BRAGLIA, AND RICCARDO BRAGLIA

37 C.F.R. §§ 131 and 132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Giorgio Calderari, Daniele Bonadeo, Roberta Cannella, Enrico Braglia and Riccardo Braglia, hereby give this declaration under 37 C.F.R. §§ 131 and 132:

1) Our names are Giorgio Calderari, Daniele Bonadeo, Roberta Cannella, Enrico Braglia and Riccardo Braglia.

2) With the exception of Enrico Braglia, we are all employed by Helsinn Healthcare SA ("Helsinn"), the assignee of the above-referenced patent application.

3) Enrico Braglia was employed by Helsinn at all times during the events described in this declaration, and left Helsinn in January 2007.

4) We are all inventors for this application. Enrico Braglia and Riccardo Braglia are also inventors of the subject matter described and claimed in WO 2004/045615 to Macciocchi, et al. (the "Macciocchi application"), and WO 2004/073714 to Baroni et al. (the "Baroni application").

5) This patent application is based on the discovery of liquid formulations of palonosetron with improved stability.

6) The formulations can be stored for prolonged periods of time in a variety of conditions without significant degradation or loss of potency, and thus are considered pharmaceutically stable.

7) The formulations were developed by us at Helsinn in the late 1990s, and were completed sometime before March 24, 1999.

8) We filed U.S.S.N. 60/444,351, which was our first patent application based on these formulations, on January 30, 2003.

9) We filed PCT application No. PCT/EP04/000888, claiming priority to the '351 application, on January 30, 2004.

10) We filed U.S.S.N. 11/186,311, claiming priority to the US '351 and PCT '888 applications, on July 21, 2005.

11) Finally, we filed three continuation applications – U.S.S.N. 11/388,268 (the '268 application), U.S.S.N. 11/388,269 (the '269 application), and U.S.S.N. 11/388,270 (the '270 application), claiming priority to the US '311 application, the US '351 application, and the PCT '888 application, on March 4, 2006.

12) Each of the foregoing applications contains the following example of an injectable Formulation of palonosetron hydrochloride:

EXAMPLE 4: FORMULATION I

Ingredient	mg/mL
Palonosetron Hydrochloride	0.05
Mannitol	41.5
EDTA	0.5
Trisodium citrate	3.7
WFJ	10.
Citric acid	1.56
Sodium hydroxide solution and/or hydrochloric acid solution	pH 5.0 ± 0.5

13) For ease of reference, we will refer to this formulation as the Example 4 formulation.

14) The Example 4 formulation was developed by us sometime before March 24, 1999, and transmitted to a

contract manufacturer for Helsinn, Oread Laboratories in Palo Alto California ("Oread"), for the production of commercial scale batches of palonosetron hydrochloride.

15) A copy of the master batch record developed by Oread for the formulation is contained in Exhibit A hereto.

16) The master batch record describes the Example 4 formulation on page 2 of 22.

17) As can be seen, the batch record has an effective date of March 24, 1999, and thus makes clear that we had developed the formulation before this date.

18) In fact, we had invented and were in possession of all of the subject matter currently claimed in U.S.S.N. 111186,311, U.S.S.N. 11/388,268, U.S.S.N. 111388,269, and U.S.S.N. 11/388,270 as of March 24, 1999, *because* we had completed stability studies for the Example .4 formulation, and understood the effect that variations in palonosetron concentration, pH, and excipient concentrations would have on the stability of the formulation.

19) Copies of the claims currently pending in U.S.S.N. 11/186,311, U.S.S.N. 11/388,268, U.S.S.N. 11/388,269, and U.S.S.N. 11/388,270 are attached as Exhibits B, C, D and E, respectively.

20) We are familiar with the work of Macciocchi et al. that is described in WO 2004/045615 (the "Macciocchi application"), and the work of Baroni et al. that is described in WO 2004/073714 (the "Baron' application").

21) In fact, declarants Enrico Braglia and Riccardo Braglia arc both named inventors of the subject matter

described and claimed in the Macciocchi and Baroni applications.

22) With the exception of Dr. Macciocchi, who recently passed away, the inventors for those patent applications are close colleagues of ours who also work at Helsinn or, in the case of Dr. Baroni, recently retired from Helsinn.

23) The Macciocchi and Baroni POT applications were filed on November 6, 2003 and February 18, 2004, respectively, which is more than four years after we first invented the Example 4 formulation, and the formulations described in U.S.S.N. 11/186,311, U.S.S.N. 11/388,268, U.S.S.N. 11/388,269, and U.S.S.N. 11/388,270.

24) At least some of the clinical studies described in the Macciocchi and Baroni applications used the Example 4 formulation.

25) Any description of pharmaceutical formulations of palonosetron described in the Macciocchi and Baroni application was derived entirely from work that we performed leading to the Example 4 formulations, and communicated by us to the inventors for the Macciocchi and Baroni application before November 15, 2002, the priority date for the Macciocchi and Baroni applications.

26) In particular, any description in the Macciocchi and Baroni applications of palonosetron formulations having a pH between 4 and 6, palonosetron concentrations between 0.01 and 2.0 or 5.0 mg/ml, the use of palonosetron hydrochloride, the use of mannitol or a chelating agent in liquid palonosetron formulations, the use of these features in an oral or intravenous formulation, the storage of these formulations for periods exceeding 3 months, 6 months, 1 year, 18

months or 2 years under varying storage conditions including room temperature, was derived entirely from the work we did leading to the Example 4 formulation.

27) All of the formulation development work described in the foregoing paragraphs was performed in Switzerland, which to my knowledge has been a member of the World Trade Organization (WTO) since July 1, 1995, and the United States.

[SIGNATURES ON FOLLOWING PAGE]

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code. I declare under penalty of perjury that the foregoing is true and correct.

/s/ Giorgio Calderari
Giorgio Calderari / Dated: November 21, 2007

s/ Daniele Bonadeo
Daniele Bonadeo Dated: November 21, 2007

/s/ Roberta Cannella
Roberta Cannella Dated: November 21, 2007

/s/ Enrico Braglia
Enrico Braglia Dated: November 21, 2007

/s/ Riccardo Braglia
Riccardo Braglia Dated: November 21, 2007

IN THE UNITED STATES PATENT
AND TRADEMARK OFFICE

IN RE APPLICATION:

MACCIOCCHI, *ET AL.*

Examiner: McMillian, Kara Renita
Serial No. 11/129,839
Art Unit: 1617

Filed: May 16, 2005

Continuation No.: 1648

For Palonosetron for the Treatment of
Chemotherapy Induced Emesis

STATUTORY DECLARATION OF SERGIO CANTOREGGI, ENRICO BRAGLIA, AND RICCARDO BRAGLIA

37 C.F.R. §§ 131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sergio Cantoreggi, Enrico Braglia and Riccardo Braglia, hereby give this declaration under 37 C.F.R. §§ 131 and 132:

1) Our names arc Sergio Cantoreggi, Enrico Braglia and Riccardo Braglia.

2) We submit this declaration to establish that Alberto Macciocchi, Enrico Braglia, and Riccardo Braglia had conceived the invention defined by claim 1 of this application, and reduced it to practice, before November 16, 2001, the date that Dr. Piraccini published abstract no. 5169 in Blood, vol. 98, no. 11 part 2.

3) In particular, we submit this declaration to establish that Alberta Macciocchi, Enrico Braglia and Riccardo Braglia had conceived the idea to use palonosetron for the treatment of acute and delayed-onset CINV, and had conducted clinical trials in humans to test this idea, at least as early as October 2, 2001.

4) Riccardo Braglia and Sergio Cantoreggi are currently employed by Helsinn Healthcare SA ("Helsinn"), the assignee of the above-referenced patent application. Enrico Braglia no longer works for Helsinn, but was employed by Helsinn at all times during the events described in this declaration.

5) Dr. Alberto Macciocchi is now deceased, but also worked for Helsinn during the events that gave rise to this patent application.

6) Attached hereto in Exhibit A is a portion of the Clinical Study Report for PALO-09-03. This report documents one of the studies that Helsinn sponsored in order to secure FDA's approval to market palonosetron in the United States.

7) As can be seen from page 1 of Exhibit A, Helsinn initiated PALO 99-03 on August 1, 2000, and completed the study on October 2, 2001.

8) As can be seen from page 2, Dr. Alberto Macciocchi was the project manager for PALO-99-03.

9) Enrico Braglia and Riccardo Braglia worked with Dr. Macciocchi as he developed the clinical protocol for PALO-99-03, participated with Dr. Macciocchi in the decision to study palonosetron for the treatment of acute and delayed-onset CINV, and worked with Dr. Macciocchi to fund and implement PALO-99-03.

10) Sergio Cantoreggi has since worked extensively with PALO-99-03, and is very familiar with the work reported in PALO-99-03.

11) We understand that this patent application claims:

> "A method of treating chemotherapy or radiotherapy-induced acute and delayed emesis in an adult human for five days after an emesis inducing chemotherapy or radiotherapy event, comprising administering to said human a single dose of a treatment-effective amount of about 0.25 mg of palonosetron in the form of palonosetron hydrochloride prior to said emesis-inducing event, without administering any further palonosetron during said five day period."

12) Exhibit A proves that we had conceived each of the features of this method, and tested the method in humans, before October 2, 2001.

13) The treatment of acute emesis during day 1 after chemotherapy was the Primary Criterion used to evaluate PALO-99-03, and is described on page 6 of Exhibit A:

> "Complete response (defined as no emetic episode and no rescue medication) during the first 24 hours after administration of chemotherapy."

14) The treatment of delayed emesis during days 2-5 was one of the Secondary Criteria used to evaluate PALO-99-03, and is described on page 6 of Exhibit A:

> "Complete response (no emetic episode and no rescue medication) daily for the 24 to 120 hour interval, for cumulative time periods and for the overall 0 to 120 hour interval, ... number of emetic episodes, time to first emetic episode, ..."

15) The use of a single dose of palonosetron hydrochloride during the five day period, in an amount of 0.25 mg. palonasetron, is described on page 4 of Exhibit A, which refers to Palonosetron HCl as the active ingredient, and the Primary Objective to test "single W doses of palonosetron 0.25 mg."

16) In all of this testing, the palonosetron was administered prior to chemotherapy being initiated.

17) Thus, we had conceived the idea to use 0.25 mg. palonosetron for the treatment of acute and delayed-onset CINV, as described in claim 1, at least as early as August 1, 2001 (the date that the study began).

18) Most important, we had successfully tested the method in human patients, and we had done so before October 2, 2001 (the date the study was completed).

19) As reported on page 8 of Exhibit A,

> "Pairwise testing revealed differences between palonosetron 0.25 mg and ondansetron in favor of palonosetron 0.25 mg. for ... number of emetic episodes on Study Days 1, 2, 3 and the time period 0 to 120 hours ..."

20) The conception and reduction to practice of this invention was performed in, among other countries, Switzerland and the United States.

I declare under penalty of perjury that all statements made herein of my own knowledge are true and that all statements made an information and belief are believed to be true, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and may jeopardize the validity of this application or any patent issuing thereon.

/s/ Sergio Cantoreggi — Dated: August 23, 2010
Sergio Cantoreggi

/s/ Enrico Braglia — Dated: August 23, 2010
Enrico Braglia

/s/ Riccardo Braglia — Dated: August 23, 2010
Riccardo Braglia

(12) United States Patent Calderari et al.

(10) Patent No.: US 8,598,219 B2

(45) Date of Patent: *Dec. 3, 2013

(54) LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

(71) Applicants: Helsinn Healthcare S.A., Lugano (CH); Roche Palo Alto LLC, Palo Alto, CA (US); Simone Macciocchi, Melide (CH); Giulio Macciocchi, Breganzona (CH)

(72) Inventors: Giorgio Calderari, Rancate (CH) Daniele Bonadeo, Casalzuigno (IT); Roberta Cannella, Varese (IT); Alberto Macciocchi, Melide (CH) Andrew Miksztal, Palo Alto, CA (US); Thomas Malefyt, Carmel Valley, CA (US); Kathleen M Lee, Palo Alto, CA (US); Carmine Panuccio. Casnate con Bernat (1T)

(73) Assignees: Helsinn Healthcare SA. Lugano/ Pazzallo (CH); Roche Palo Alto LLC, Palo Alto, CA (US)

(*) Notice: Subject to any disclaimer, the terms of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: 13/901,437

(22) Filed: May 23, 2013

(65) Prior Publication Data

US 2013/0261592 Al Oct. 3, 2013

Related US. Application Data

(63) Continuation-in-part of application No. 13/087,012, filed on Apr. 14, 2011, now Pat. No.

8,518,981, which is a continuation of application No. 11/186,311, filed on Jul. 21, 2005, now Pat. No. 7,947,724, which is a continuation of application No. PCT/EP2004/000888, filed on Jan. 30, 2004.

(60) Provisional application No. 60/444,351, filed on Jan. 30. 2003.

(51) Int. Cl.

A01N 43/52 (2006.01)

(52) U.S. Cl.

USPC 514/397

(58) Field of Classification Search

USPC 514/397

See application file for complete search history.

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Primary Examiner—Shirley Gembeh

(74) *Attorney, Agent. or Firm*—Clark G. Sullivan; Troutman Sanders LLP

(57) ABSTRACT

The present invention relates to shelf-stable liquid formulations of palonosetron for reducing chemotherapy and radiotherapy induced emesis with palonosetron. The formulations are particularly useful in the preparation of intravenous and oral liquid medicaments.

8 Claims, No Drawings

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Defendants Aurobindo Pharma Ltd.'s and Aurobindo Pharma USA Inc.'s Answer, Affimative Defenses, and

Counterclaims, dated Aug. 23, 2013 (D. Del. Case No. 13-688).

Plaintiff's Answer to the Counterclaims of Aurobindo Pharma USA Inc. and Aurobindo Pharma Ltd., dated Sep. 13, 2013 (D. Del. Case No. 13-688).

Aurobindo Pharma Ltd. Paragraph IV notice regarding U.S Patent No. 8,518,981, dated Sep. 19, 2013.

Dr. Reddy's Laboratories, Ltd.'s and Dr. Reddy's Laboratories, Inc.'s Amended Invalidity Contentions Pursuant to L. Pat. R. 3.6(c). dated Jul. 8, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579 consolidated).

Plaintiffs' Responses to Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.'s Amended Invalidity Contentions, dated Aug. 19, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).

Sandoz Inc.'s Second Amended Invalidity Contentions Pursuant to L. Pat. R. 3.7, dated Jul. 5, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).

Plaintiffs' Responses to Sandoz Inc.'s Second Amended Invalidity Contentions, dated Aug. 19, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).

Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.'s First Amended Invalidity Contentions Pursuant to L. Pat. R. 3.6(c), dated Jul. 5, 2013 (D. N. J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).

Plaintiffs' Responses to Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.'s First Amended Invalidity Contentions, dated Aug. 19, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation redacted).

Opening Expert Report of Dr. Bert Spilker, dated Sep. 9, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).

Expert Report of David G. Franc, Pharm.D., dated Sep. 5, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).

Expert Report of Lee Kirsch, Ph.D., dated Sep. 9, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).

Expert Report of Patrick P. DeLuca, Ph.D., dated Sep 9, 2013 (D.N J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).

Expect Report of Paul Myrdal, Ph.D., dated Sep. 9, 2013 (D.N.J. Case Nos. 11-3962 and 11-5579; consolidated) (confidentiality designation and other portions redacted).

Complaint for patent infringement filed by Helsinn Healthcare S.A. and Roche Palo Alto LLC against Ben Venue Laboratories, Inc. d/b/a Bedford Laboratories regarding U.S. Patent Nos. 7,947,724, 7,947,725, 7,960,424, and 8,518,981 dated Sep. 25, 2013 (D. Del. Case No. 13-1612).

Complaint for patent infringement filed by Helsinn Healthcare S.A. and Roche Palo Alto LLC against Dr.

Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories, Inc., Sandoz Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. regarding U.S. Patent No.8,518,981 dated Sep. 30, 2013 (D.N.J. Case No. (13-5815)),

* cited by examiner

LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON

FIELD OF THE INVENTION

The present invention relates to shelf-life stable liquid formulations of palonosetron that are especially useful in the preparation of injectable and oral medicaments.

BACKGROUND OF THE INVENTION

Emesis is a devastating consequence of cytotoxic therapy, radiotherapy, and post-operative environments that drastically affects the quality of life of people undergoing such treatments. In recent years a class of drugs referred to as 5-HT_3 (5-hydroxytryptamine) receptor antagonists has been developed that treat such emesis by antagonizing cerebral functions associated with the 5-HT_3 receptor. See *Drugs Acting on 5-Hydroxytryptamine Receptors:* The Lancer Sep. 23, 1989 and references cited therein. Drugs within this class include ondansetron, granisetron, alosetron, tropisetron, and dolasetron. These 5-HT_3 antagonists are often administered intravenously shortly before chemotherapy or radiotherapy is initiated, and can be administered more than once during a cycle of chemotherapy or radiotherapy. In addition, they are often supplied as tablets or oral elixirs to either supplement an intravenous administration, or to ease

home usage of the drug if the patient is self-administering the chemotherapeutic regimen.

Because some chemotherapeutic agents can induce emesis over extended periods of several days even when they are administered only once, it would be desirable to administer an emesis-inhibiting drug such as a 5-HT_3 antagonist every day until the risk of emesis has substantially subsided. The present class of 5-HT_3 antagonists has not proven especially helpful meeting this need, however, because the $5HT_3$ receptor antagonists currently marketed have proven to be less effective in controlling delayed nausea and vomiting than they are at controlling acute emesis. Sabra, K, *Choice of a $5HT_3$ Receptor Antagonist for the Hospital Formulary.* EHP, October 1996: 2 (suppl 1):S19-24.

Recently, clinical investigations have been made concerning palonosetron, a new 5-HT_3 receptor antagonist reported in U.S. Pat. No. 5,202,333. These investigations have shown that the drug is an order of magnitude more potent than most existing 5-HT_3 receptor antagonists, has a surprising half-life of about 40 hours, and is effective to reduce delayed-onset nausea induced by chemotherapeutic agents. However, formulating palonosetron in liquid formulations has not proven an easy task, typically due to shelf-stability issues. U.S. Pat. No. 5,202,333 discloses an intravenous formulation of palonosetron in example 13 that contains the following ingredients:

Ingredient	Mg
Palonosetron HCl	10-100 mg.
Dextrose Monohydrate	q.s. to make Isotonic
Citric Acid Monohydrate	1.05 mg.
Sodium Hydroxide	0.18 mg.
WFI	To 1.0 ml.

The formulation has a pH of 3,7 and a shelf stability of less than the 1-2 year time period required by health authorities in various countries.

Ondansetnon, its uses, and medicaments made with ondansetron are disclosed in U.S. Pat. Nos. 4,695,578, 4,753,789, 4,929,632, 5,240,954, 5,344,658, 5,578,628, 5,578,632, 5,922,749, 5,622,720, 5,955,488, and 6,063,802. Commercially it is distributed by GlaxoSmithKline as Zofran® and is indicated for prevention of postoperative nausea and vomiting (PONV), cancer chemotherapy-induced nausea and vomiting (CINV), and radiotherapy-induced nausea and vomiting (RINV) and it is available as an injection, tablets and solution, and as Zofran ODT® (ondansetron) Orally Disintegrating Tablets.

Granisetron, its uses, and medicaments made with granisetron are disclosed in U.S. Pat. Nos. 4,886,808, 4,937,247, 5,034,398 and 6,294,548. Commercially it is distributed by Roche Laboratories Inc. as Kytril®, indicated for the prevention of nausea and vomiting associated with chemotherapy or radiation therapy, and is offered in tablet form, oral solution, and as an injection.

Alosentron, its uses, and medicaments made with alosetron are disclosed in U.S. Pat. Nos. 5,360,800 and 6,284,770. Commercially it is distributed by GlaxoSmithKline as Lotrunex®.

Tropisetron is commercially available as Navoban® (Novartis) CAS-89565-68-4 (tropisetron); CAS-105826-92-4 (tropisetron hydrochloride) and it is indicated for treatment of PONV and CINV.

Dolasetron, its uses, and medicaments made with ondansetron are disclosed in U.S. Pat. Nos. 5,011,846, and 4,906,755. Commercially it is distributed by Aventis Pharmaceuticals Inc. as Anzemet®, indicated for prevention of both PONV and CINV, and it is offered in the form of a tablet or an intravenous solution.

Therefore, there exists a need for a palonosetron formulation with increased stability and thereby increased shelf life. There also exists a need for an appropriate range of concentrations for both the 5-HT_3 receptor antagonist and its pharmaceutically acceptable carriers that would facilitate making a formulation with this increased stability.

It is an object of the present invention to provide a formulation of Palonosetron hydrochloride with increased pharmaceutical stability for preventing and/or reducing emesis.

It is another object of the invention to provide an acceptable range of concentrations which will stabilize a formulation containing Palonosetron hydrochloride.

It is a further object of the invention to provide a formulation of Palonosetron which would allow for prolonged storage.

It is also an object of the invention to provide a formulation of Palonosetron which would allow terminal sterilization.

SUMMARY OF THE INVENTION

The inventors have made a series of discoveries that support a surprisingly effective and versatile formulation for the treatment and prevention of emesis using palonosetron. These formulations are shelf stable for periods greater than 24 months at mom temperature, and thus can be stored without refrigeration, and manufactured using non-aseptic, terminal sterilization processes.

In one aspect, the inventors have discovered that formulations which include the active ingredient palonosetron require in same instances only 1/10th the amount of other previously known compounds for treating emesis, which surprisingly allows the use of concentrations of palonosetron far below those that would ordinarily be expected. Thus, in one embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising a) from about 0.01 mg/mL to about 5 mg/mL palonosetron or a pharmaceutically acceptable salt thereof, and b) a pharmaceutically acceptable carrier.

The inventors have further discovered that by adjusting the formulation's pH and/or excipient concentrations it is possible to increase the stability of palonosetron formulations. Therefore, in another embodiment, the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising a) palonosetron or a pharmaceutically acceptable salt thereof; and b) a pharmaceutically acceptable carrier, at a pH from about 4.0 to about 6.0. In another embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising from about 0.01 to about 5.0 mg/ml palonosetron ore pharmaceutically

acceptable salt thereof; from about 10 to about 100 millimoles citrate buffer; and from about 0.005 to about I.0 mg/ml E respondentDTA.

The inventors have further discovered that the addition of mannitol and a chelating agent can increase the stability of palonosetron formulations. Therefore, in still another embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emetic comprising a) palonosetron or a pharmaceutically acceptable salt thereof and b) a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises a chelating agent and mannitol,

DETAILED DESCRIPTION OF THE INVENTION

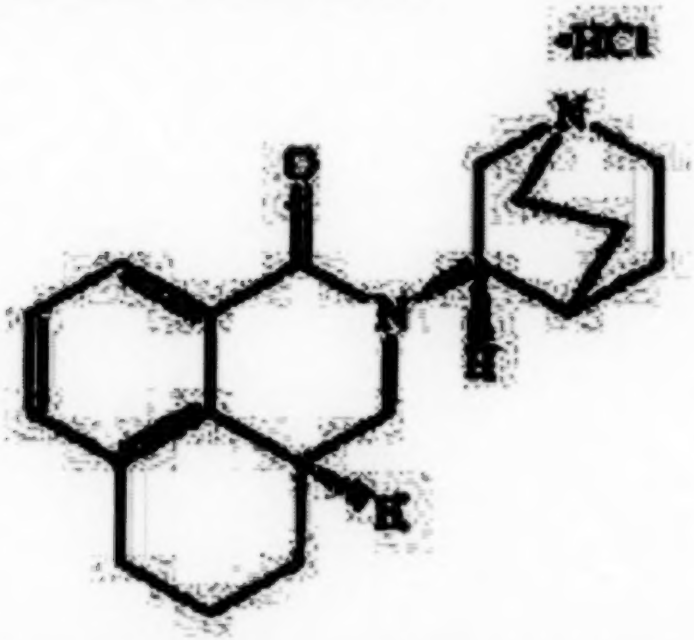
Definitions

"Vial" means a small glass container sealed with the most suitable stopper and seal, other suitable primary containers may be used, for instance, but not limited to, pre-filled syringes. Vial also means a sealed container of medication that is used one time only, and includes breakable and nonbreakable glass vials, breakable plastic vials, miniature screw-top jars, and any other type of container of a size capable of holding only one unit dose of palonosetron (typically about 5 mls.).

Throughout this specification the word "comprise," or variations such as "comprises" or "comprising," will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of' any other element, integer or step, or group of elements, integers or steps

"Palonsetron" means (3aS)-2,3,3a,4,5,6-Hexahydro-2-[(S)-1-Azabicyclo[2.2.2]oct-3-yl]2,3,3a,4,5,6-

hexahydro-1-oxo-[Hbenz[de]isoquinoline, and is preferably present as the monohydrochloride. Palonosetron monohydrochloride can be represented by the following chemical structure:



Concentrations—When concentrations of palonosetron are given herein, the concentration is measured in terms of the weight of the free base. Concentrations of all other ingredients are given based on the weight of ingredient added to the solution.

"Pharmaceutically acceptable" means that which is useful in preparing a pharmaceutical composition that is generally safe, non-toxic and neither biologically nor otherwise undesirable and includes that which is acceptable for veterinary use as well as human pharmaceutical use.

"Pharmaceutically acceptable salts" means salts which are pharmaceutically acceptable, as defined above, and which possess the desired pharmacological activity. Such salts include acid addition salts formed with inorganic acids such as hydrochloric acid, hydrobromic acid, sulfuric acid, nitric acid, phosphoric acid, and the like; or with organic acids such as acetic acid, propionic acid, hexanoic acid, heptanoic acid, cyclopentanepropionic acid, glycolic acid, pyruvic acid, lactic acid, malonic acid, succinic acid, malic acid, maleic acid, fumaric acid, tartaric acid, citric acid, benzoic acid, o-(4-hydroxybenzoyl)benzoic acid, cinnamic acid, mandelic acid, methanesulfonic acid, ethanesulfonic acid, 1,2,-ethanedisulfonic acid, 2-hydroxyethanesulfonic acid, benzenesulfonic acid p-chlorobenzenesulfonic acid, 2-naphthalenesulfonic acid, p-toluenesulfonic acid, camphorsulfonicacid, 4-methylbicyclo[2.2.2]oct-2-ene-carboxylic acid, glucoheptonic acid, 4.4'-methylenebis(3-hydroxy-2-ene-1-carboxylic acid), 3-phenylpropionic acid, trimethylacetic acid, tertiary butylacetic acid, lauryl sulfuric acid, gluconic acid, glutamic acid, hydroxynaphthoic acid, salicylic acid, stearie acid, muconic acid, and the like.

In addition, pharmaceutically acceptable salts may be formed when an acidic proton present is capable of reacting with inorganic or organic bases. Acceptable inorganic bases include sodium hydroxide, sodium carbonate, potassium hydroxide, aluminum hydroxide and calcium hydroxide. Acceptable organic bases include ethanolamine, diethanolamime, triethanolamine, tromethamine, N-methylglucamine and the like.

Discussion

The fact that palonosetron can be formulated in some instances at concentrations of only about 1/10th the amount of other previously known compounds for treating emesis, surprisingly allows the use of concentrations of palonosetron far below those that would ordinarily be expected. Thus, in one embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising a) from about 0.01 mg/mL to about 5 mg/mL palonosetron or a pharmaceutically acceptable sill thereof; and b) a pharmaceutically acceptable carrier. Similarly. in another embodiment the invention provides a method of formulating a pharmaceutically stable solution of palonosetron comprising admixing from about 0.01 mg/mL to about 5 mg/mL palonosetron or a pharmaceutically acceptable salt thereof; with a pharmaceutically acceptable carrier. In alternative embodiments, the formulation includes palonosetron or a pharmaceutically acceptable salt thereof in a concentration from about 0.02 mg/mL to about 1.0 mg/mL, from about 0.03 mg/mL to about 0.2 mg/mL, and most optimally about 0.05 mg/ml.

A particular advantage associated with the lower dosages of intravenous palonosetron is the ability to administer the drug in a single intravenous bolus over a short, discrete time period. This time period generally extends from about 10 to about 60 seconds, or about 10 to about 40 seconds, and most preferably is about 10 to 30 seconds. In one particular embodiment the palonosetron is supplied in vials that comprise 5 ml, of solution, which equates to about 0.25 mg of palonosetron at a concentration of about 0.05 mg/ml.

The inventors have further discovered that by adjusting the formulation's pH and/or excipient concentrations it is possible to increase the stability of palonosetron formulations. Therefore, in another embodiment, the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising a) palonosetron or a pharmaceutically acceptable salt thereof; and b) a pharmaceutically acceptable carrier, at a pH from about 4.0 to about 6.0. Similarly, in another embodiment the invention provides a method of formulating a pharmaceutically stable solution of palonosetron comprising admixing a) palonosetron or a pharmaceutically acceptable salt thereof; and b) a pharmaceutically acceptable carrier, at a pH from about 4.0 to about 6.0. In alternative embodiments, the pH is from ahem 4.5 to about 5.5, and most optimally about 5.0. There are many examples to those of skill in the art of suitable solutions to adjust the pH of a formulation. Two exemplary solutions are sodium hydroxide and hydrochloric acid solution, either of which could be used to adjust the pH of the formulation,

In another embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising from about 0.01 to about 5.0 mg/ml palonosetron or a pharmaceutically acceptable salt thereof and (i) from about 10 to about 100 millimoles citrate buffer, and/or (ii) from about 0.005 to about 1.0 mg/ml EDTA. Similarly, in another embodiment the invention provides a method of formulating a pharmaceutically stable solution of palonosetron comprising admixing from about 0.01 to about 5.0 mg/ml palonosetron or a pharmaceutically acceptable salt thereof and (i) from about 10 to about 100 millimoles citrate buffer, and/or (ii) from about 0.005 to about 1.0 mg/ml EDTA. The citrate buffer can

be in the form of citric acid and/or a salt of citric acid such as trisodium citrate. In various embodiments, the ranges of one or more of the foregoing ingredients can be modified as follows:

The formulation may comprise palonosetron or a pharmaceutically acceptable salt thereof in a concentration from about 0.02 mg/mL to about 1.0 mg/mL, from about 0.03 mg/mL to about 0.2 mg/mL palonosetron hydrochloride, and most optimally about 0.05 mg/ml.

The formulation may comprise citrate buffer in a concentration of from about 10 to about 40 millimoles, or 15-30 millimoles.

The formulation may comprise EDTA in a concentration of from about 0.005 mg/ml to about 1.0 mg/ml, or about 0.3 to about 0.7 mg/ml, and most optimally about 0.5 mg/ml.

The inventors have further discovered that the addition of mannitol and a chelating agent can increase the stability of palonosetron formulations. Therefore, in still another embodiment the invention provides a pharmaceutically stable solution for preventing or reducing emesis comprising a) palonosetron or a pharmaceutically acceptable salt thereof and b) a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises a chelating agent and mannitol. Similarly, in another embodiment the invention provides a method of formulating a pharmaceutically stable solution of palonosetron comprising admixing a) palonosetron or a pharmaceutically acceptable salt thereof and b) a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises a chelating agent and mannitol. The chelating agent is

preferably EDTA, and, in various embodiments the chelating agent is present in a concentration of from about 0.005 to about 1.0 mg/mL or from about 0.05 mg/mL to about 1.0 mg/mL or from about 0.3 to about 0.7 mg/ml, or most optimally about 0.5 mg/ml. In various embodiments the mannitol is present in a concentration of from about 10.0 mg/ml to about 80.0 mg/ml, from about 20.0 mg/ml to about 60.0 mg/ml, or from about 40.0 to about 45.0 mg/ml.

Injectable formulations are typically formulated as aqueous solutions in which water is the primary excipient. Oral formulations will differ from injectable formulations generally by the additional presence of flavoring agents, coloring agents, or viscosity agents. Natural or synthetic sweeteners include, among others, mannitol, sorbitol, saccharose, saccharine, aspartame, acelsulphame K. or cyclamate. These agents are generally present in concentrations in excess of 100 mg/ml or 250 mg/ml when used as sweetening agents, in contrast to the 41.5 mg/ml concentration of mannitol described in some of the embodiments of the invention. in which mannitol is acting simply as a tonicifying agent.

The formulations of the present invention are particularly suited for use in injectable and oral liquid formulations, but it will be understood that the solutions may have alternative uses. For example, they may be used as intermediates in the preparation of other pharmaceutical dosage forms. Similarly, they may have other routes of administration including intranasal or inhalation. Injectable formulations may take any route including intramuscular, intravenous or subcutaneous,

Still further embodiments relate to improvements in the ease with which the palonosetron formulation can

be stored or manufactured. In particular, the inventors have discovered that the formulations of the present invention allow storage of the product for extended periods at room temperature. Thus, in yet another embodiment the invention provides a method of storing one or more containers in which are contained a solution of palonosetron or a pharmaceutically acceptable salt thereof comprising: a) providing a room comprising said one or more containers; b) adjusting or maintaining the temperature of the room at greater than about ten, 15, or 20 degrees celcius; and c) storing said containers in said room for one month, 3 months, 6 months, one year, 18 months, 24 months or more (but preferably not exceeding 36 months), wherein (i) the palonosetron or pharmaceutical salt thereof is present in a concentration of from about 0.01 mg/mL to about 5.0 mg/ml, (ii) the pH of the solution is from about 4.0 to about 6.0, (iii) the solution comprises from about 0.01 to about 5.0 mg/ml palonosetron or a pharmaceutically acceptable salt thereof, from about 10 to about 100 millimoles citrate buffer and from about 0.005 to about 1.0 mg/ml EDTA, (iv) the solution comprises a chelating agent, or (v) the solution comprises from about 10 about 100 millimoles of a citrate buffer.

The stability of the foregoing formulations also lends itself well to terminal sterilization processes in the manufacturing process. Therefore, in still another embodiment the invention provides a method of filling a container in which is contained a solution of palonosetron or a pharmaceutically acceptable salt thereof comprising: a) providing one or more sterile open containers (preferably 5 ml. vials) filling said containers with a solution of palonosetron in a non-aseptic environment: c) sealing said filled containers; and d) sterilizing said sealed, filled containers,

wherein (i) the palonosetron or pharmaceutical salt thereof is present in a concentration of from about 0.01 mg/mL to about 5 mg/mL, (ii) the pH of the solution is from about 4.0 to about 6.0. (iii) the solution comprises from about 0.01 to about 5.0 mg/ml palonosetron or a pharmaceutically acceptable salt thereof, from about 10 to about 100 millimoles citrate buffer and from about 0.005 to about 1.0 mg/ml EDTA, (iv) the solution comprises a chelating agent, or (v) the solution comprises from about 10 to about 100 millimoles of a citrate buffer.

EXAMPLES

Example 1

Stabilizing pH

A study was conducted to determine the effect of pH on formulations containing palonosetron hydrochloride, measuring stability at 80° C, at pH 2.0, 5.0, 7.4, and 10.0. The results indicated that palonosetron hydrochloride is most stable at pH 5.0.

Example 2

Stabilizing Concentration Ranges

A formulation optimization study was performed using an experimental design software. Twenty-four lots of drug product were analyzed to investigate the appropriate concentration ranges for palonosetron hydrochloride (0.05 mg/ml to 5.0 mg/ml). citrate buffer (0 to 80 mM) and EDTA (0 to 0.10%). The level of EDTA and citrate buffer were selected based on the optimal formulation, which was shown to be formulated with EDTA 0.05% and 20 mM citrate buffer at pH 5.0. The results of this study indicated that palonosetron concentration was also a critical

factor in chemical stability, with greatest stability seen at the lowest palonosetron concentration.

Example 3

Tonicifying Agent

Formulations of palonosetron hydrochloride in citrate buffer were prepared including either a) sodium chloride or b) mannitol. The palonosetron hydrochloride formulation including mannitol showed superior stability. The optimum level of mannitol required for an isotonic solution was found to be 4.15%.

Example 4

Formulation I

The following is a representative pharmaceutical formulation containing palonosetron that is useful for intravenous formulations, or other liquid formulations of the drug.

Ingredient	mg/mL
Palonosetron Hydrochloride	0.05*
Mannitol	41.5
EDTA	0.5
Trisodium citrate	3.7
Citric acid	1.56
WFJ	q.s. to 1 ml
Sodium hydroxide solution and/or hydrochloric acid solution	pH 5.0 ± 0.5

*calculated as a free base

Example 5

Formulation II

The following is a representative pharmaceutical formulation containing palonosetron that is useful for oral formulations, or other liquid formulations of the drug.

Ingredient	mg/mL
Palonosetron Hydrochloride	0.05*
Mannitol	150
EDTA	0.5
Triaodium citrate	3.7
Citric acid	1.56
WFJ	q.s. to 1 ml
Sodium hydroxide solution and/or hydrochloric acid solution	pH 5.0 = 0.5
Flavoring	q.s.

*calculated as a free base

Example 6

Stability of Palonosetron without Dexamethasone

The physical and chemical stability of palonosetron HCI was studies in concentrations of 5 μg/mL and 30 μg/mL in 5% dextrose injection, 0.9% sodium chloride injection, 5% dextrose in 0.45% sodium chloride injection, and dextrose 5% in lactated Ringer's injection. The admixtures were evaluated over 14 days at 4° C, in the dark and for 48 hours at 23° C, under fluorescent light.

Test samples of palonosetron HCI were prepared in polyvinyl chloride (PVC) bags of the infusion solutions

at concentrations of 5 and 30 μg/mL. Evaluations for physical and chemical stability were performed on samples taken initially and after 1, 3, 5, 7, and 14 days of storage at 4° C, and after 1, 4, 24, and 48 hours at 23° C. Physical stability was assessed using visual observation in normal room light and using a high-intensity monodirectional light beam. In addition, turbidity and particle content were measured electronically. Chemical stability of the drug was evaluated by using a stability-indicating high performance liquid chromatographic (HPLC) analytical technique.

All samples were physically stable throughout the study. The solution remained clear, and little or no change in particulate burden and haze level were found. Additionally, little or no loss of palonosetron HCI occurred in any of the samples at either temperature throughout the entire study period.

Example 7

Stability of Palonosetron with Dexamethasone

The physical and chemical stability of palonosetron 0.25 mg admixed with dexamethasone (as sodium phosphate) 10 mg or 20 mg in 5% dextrose injection or 0.9% sodium chloride injection in polyvinyl chloride (PVC) minibags, and also admixed with dexamethasone (as sodium phosphate) 3.3 mg in 5% dextrose injection or 0.9% sodium chloride injection in polypropylene syringes at 4° C. In the dark for 14 days and at 23° C, exposed to normal laboratory fluorescent light over 48 hours, was studied.

Test samples of palonosetron HCI 5 μg/mL with dexamethasone (as sodium phosphate) 0.2 mg/mL and also 0.4 mg/mL were prepared in polyvinyl chloride (PVC) mini bags of each infusion solution.

Additionally, palonosetron HCI 25 μg/mL with dexamethasone (as sodium phosphate) 0.33 mg/mL in each infusion solution were prepared as 10 mL of test solution in 20-mL polypropylene syringes. Evaluations for physical and chemical stability were performed on samples taken initially and after 1, 3, 7. and 14 days of storage at 4° C. and after 1, 4, 24, and 48 hours at 23° C. Physical stability was assessed using visual observation in normal room light and using a high-intensity monodirectional tight beam. In addition, turbidity and particle content were measured electronically. Chemical stability of the drug was evaluated by using a stability-indicating high performance liquid chromatographic (HPLC) analytical technique.

All samples were physically compatible throughout the study. The solutions remained dear, and little or no change in particulate burden and haze level were found. Additionally, little or no loss of palonosetron HCI and dexamethasone occurred in any of the samples at either temperature throughout the entire study period.

Example 8

Formulation III

The following is a representative pharmaceutical formulation and container closure for palonosetron that is useful for intravenous infusion formulations.

Ingredient	Amount (mg)
Palonosetron Hydrochloride	0.75[a)]
Sodium Chloride	450.0
EOM	225
Sodium citrate	18.5
Citric acid monohydrate	7.8
WFJ	q.s. to 50 mL
Sodium hydroxide solution and/or hydrochloric acid solution	pH 4.8 ± 0.5
Container closure system	plastic container[b)] plus rubber stopper[c)]

[a)] Calculated based on the weight of free base

[b)] Polyethylene multilayer film infusion bag.

[c)] Isoprene rubber stopper

This invention has been described with reference to its preferred embodiments. Variations and modifications of the invention will be obvious to those skilled in the art from the foregoing detailed description of the invention.

What is claimed is:

1. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

from 0.005 mg/mL to 1.0 mg/mL EDTA; and

from 10 mg/mL to 80 mg/mL mannitol.

wherein said formulation is stable at 24 months when stored at room temperature.

2. The pharmaceutical formulation of claim 1, wherein said EDTA is in an amount of 0.5 mg/mL.

3. The pharmaceutical formulation of claim 1, wherein said mannitol is in an amount of 41.5 mg/mL.

4. The pharmaceutical formulation of claim 1, wherein said solution further comprises a citrate buffer.

5. The pharmaceutical formulation of claim 4 wherein said citrate buffer is at a concentration of 20 millimolar.

6. The pharmaceutical formulation of claim 1, wherein said solution is buffered at a pH of 5.0 ± 0.5.

7. The pharmaceutical formulation of claim 1, wherein said EDTA is in an amount of 0.5 mg/mL, wherein said mannitol is in an amount of 41.5 mg/mL, wherein said solution further comprises a citrate buffer at a concentration of 20 millimolar, and wherein said solution is buffered at a pH of 5.0 ± 0.5.

8. A pharmaceutical single-use, unit-dose formulation for intravenous administration to a human to reduce the likelihood of cancer chemotherapy-induced nausea and vomiting, comprising a 5 mL sterile aqueous isotonic solution, said solution comprising:

palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base;

from 0.005 mg/mL to 1.0 mg/mL EDTA; and

from 10 mg/mL to 80 mg/mL mannitol, wherein said formulation is stable at 18 months when stored at room temperature.

No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR THE PETITIONER

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QUESTION PRESENTED

Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

CORPORATE DISCLOSURE STATEMENT

Petitioner Helsinn Healthcare S.A. is a subsidiary of Helsinn Holding S.A. Helsinn Holding S.A. has no parent corporation, and no publicly held company holds 10% or more of its stock.

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In the Supreme Court of the United States

No. 17-1229

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 17a-52a) is reported at 855 F.3d 1356. The opinion of the district court (Pet. App. 235a-241a) is unreported. The supplemental opinion of the district court (Pet. App. 53a-231a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on May 1, 2017. A petition for rehearing was denied on January 16, 2018 (Pet. App. 1a-16a). The petition for a writ of certiorari was filed on February 28, 2018, and granted on June 25, 2018. This Court has jurisdiction under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

1. Section 3(b)(1) of the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, 285-286 (2011), provides:

> Section 102 of title 35, United States Code, is amended to read as follows:
>
> * * *
>
> (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
>
> (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention[.]
>
> * * *
>
> (b) EXCEPTIONS.—
>
> (1) DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—
>
> (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
>
> (B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.
>
> * * *

2. Section 3(a) of the AIA, 125 Stat. 285, provides:

DEFINITIONS.—Section 100 of title 35, United States Code, is amended—

* * *

(2) by adding at the end the following:

* * *

(j) The term 'claimed invention' means the subject matter defined by a claim in a patent or an application for a patent.

* * *

STATEMENT

In 2011, Congress enacted the Leahy-Smith America Invents Act (AIA) to "improve the United States patent system and promote harmonization of the United States patent system" with the patent systems of other countries. Pub. L. No. 112-29, § 3(p), 125 Stat. 284, 293. The keystone of that legislation was a change in the rules governing priority—that is, who among competing inventors has the right to patent a claimed invention. Before the AIA, the first inventor had priority. In the AIA, Congress changed that rule: joining the world's other major patent systems, Congress gave priority to the first inventor to file a patent application, regardless of the date of invention.

A critical component of Congress's shift from a first-to-invent system to a first-inventor-to-file system was a new definition of prior art—the universe of existing knowledge against which an invention's patentability is measured. Before the AIA, a patent could not issue if an "invention was * * * in public use or *on sale* in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. 102(b)

(2006) (emphasis added). Congress modified that provision in various respects in the AIA, providing, as is relevant here, that an inventor is entitled to a patent unless "the claimed invention was * * * in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention." 35 U.S.C. 102(a)(1) (emphasis added).

The new catch-all provision informs the meaning of the language that precedes it, clarifying that a sale qualifies as prior art only if the sale makes the claimed invention "available to the public." The Senate committee that first introduced the catch-all provision confirmed that interpretation, as did the AIA's sponsors. And the Patent and Trademark Office (PTO) has embraced that interpretation, both in examination guidelines issued shortly after the AIA's enactment and as an amicus curiae in this case.

But in a decision "untethered to the statutory text" of the patent laws, *Limelight Networks, Inc.* v. *Akamai Technologies, Inc.*, 134 S. Ct. 2111, 2120 (2014), the Federal Circuit disagreed. Without making any meaningful effort to come to grips with the relevant statutory language, the Federal Circuit held that public disclosure of the *fact* of a commercial sale invalidates a patent, even if the claimed invention remains secret and thus is not "available to the public." That decision flouts the AIA's plain text; it is contrary to the expressed intent of the AIA's drafters; and it would frustrate the policies that the patent laws promote. Rarely does a court of appeals veer so far off course when interpreting a federal statute. The judgment of the Federal Circuit should be reversed.

A. Background

1. Nearly two centuries ago, this Court held that an inventor's "voluntary act or acquiescence in the public sale and use" of his invention before the filing of a patent

application is an "abandonment of his right." *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1, 24 (1829). The principle that a sale could bar the issuance of a patent, known as the on-sale bar, was motivated by a "reluctance to allow an inventor to remove existing knowledge from public use." *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55, 64 (1998). Congress first codified the on-sale bar in the Patent Act of 1836. See Pub. L. No. 24-357, § 6, 5 Stat. 117.

As enacted by the Patent Act of 1952 (and unchanged until the AIA), the statutory provision containing the on-sale bar stated that a patent could not issue if an "invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. 102(b) (2006). Construing that provision in *Pfaff*, *supra*, this Court held that two conditions must be satisfied for an invention to be "on sale": first, "the product must be the subject of a commercial offer for sale," and, second, "the invention must be ready for patenting." 525 U.S. at 67.

Of particular relevance here, both before and after this Court's decision in *Pfaff*, the Federal Circuit held that an inventor's sale of an invention to another party could constitute a qualifying "commercial offer for sale" even if it did not disclose the invention to the public. See, *e.g.*, *Special Devices, Inc.* v. *OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001); *In re Caveney*, 761 F.2d 671, 675-676 (Fed. Cir. 1985). That holding was in tension with this Court's repeated statements that the on-sale bar reached the "public sale of an unpatented article" that placed the article "in public commerce." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 148-149 (1989); see, *e.g.*, *Pfaff*, 525 U.S. at 64; *Pennock*, 27 U.S. at 23-24.

2. a. In 2011, Congress transformed the Nation's patent laws by enacting the AIA. See *Kappos* v. *Hyatt*, 566

U.S. 431, 434 n.1 (2012). The AIA's fundamental innovation was to replace the existing first-to-invent patent system with a first-inventor-to-file system. That change brought the American patent system in line with the world's other major patent systems.

As part of the shift to the first-inventor-to-file system, Congress amended the definition of prior art, which plays a foundational role in patent law. A patent is an exchange between the public and an inventor. The public gets a new and useful invention; the inventor receives exclusive rights to the invention for a limited time. Prior art is the universe of existing knowledge against which an invention's patentability is measured in order to determine whether the public has received the benefit of its bargain. If an invention is novel (*i.e.*, not "already available to the public") and nonobvious (*i.e.*, not "readily discern[able] from publicly available material"), then the invention may be patented, provided that the inventor discloses the invention in the patent and satisfies the other statutory requirements. *Bonito Boats*, 489 U.S. at 150.

In the AIA, Congress amended the statutory provision defining prior art and containing the on-sale bar. As amended by the AIA, that provision, entitled "Novelty; prior art," states that a person shall be entitled to a patent unless "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention," subject to exceptions not applicable here. 35 U.S.C. 102(a)(1).

The AIA's definition of prior art differs from its pre-AIA counterpart in three critical respects. First, and of most importance here, Congress added the catch-all phrase "or otherwise available to the public" after the phrases "in public use" and "on sale." Second, Congress eliminated the pre-AIA requirement that an invalidating

public use or sale occur "in this country." And third, Congress replaced the term "invention" with the phrase "claimed invention," which it separately defined as "the subject matter defined by a claim in a patent or an application for a patent." 35 U.S.C. 100(j).

b. The legislative history reflects that, in adding the catch-all phrase "or otherwise available to the public," Congress intended to eliminate so-called "secret sales" (*i.e.*, sales that did not make inventions available to the public) as prior art—despite the Federal Circuit decisions that had held such sales to be sufficient under the pre-AIA on-sale bar. See Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 466-475 (2012).

The phrase "or otherwise available to the public" originated in the Senate Judiciary Committee, which explained that it was adding the phrase both to "emphasize the fact that [prior art] must be publicly available" and specifically to clarify that "secret collaborative agreements, which are not available to the public, are not prior art." S. Rep. No. 259, 110th Cong., 2d Sess. 9, 39 (2008). After the Senate bill passed, the House Judiciary Committee considered a revised bill that became the AIA. The House bill contained the same catch-all phrase, and the House Judiciary Committee echoed the explanation that the phrase was intended to "emphasize the fact that [prior art] must be publicly accessible." H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. I, at 42-43 & n.20 (2011).

Several of the AIA's sponsors, including the two eponymous sponsors, reiterated the point in extensive floor statements. Senator Kyl explained that the new catch-all phrase operated on the preceding phrases, including "on sale," thus "limit[ing] all non-patent prior art to that which is available to the public." 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011). Senator Leahy, the lead sponsor

in the Senate, similarly explained that the statute would "do away with precedent under current law that private offers for sale or private uses or secret processes * * * may be deemed patent-defeating prior art." 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011). Representative Lamar Smith, the lead sponsor in the House, added that, "contrary to current precedent, in order to trigger the bar in the new [Section] 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date." 157 Cong. Rec. H4429 (daily ed. June 22, 2011).

3. Following the AIA's enactment, the Patent and Trademark Office issued revised guidelines for examining patent applications. See 78 Fed. Reg. 11,059 (Feb. 14, 2013). Of particular relevance here, the PTO instructed its examiners that, under the AIA, a sale "must make the invention available to the public" to be prior art. *Id.* at 11,075. The PTO explained that sales "among individuals having an obligation of confidentiality to the inventor" do not qualify as prior art under the AIA. *Ibid.* The PTO later incorporated its interpretation into the Manual of Patent Examining Procedures, stating that the catch-all phrase "indicates that [Section 102(a)(1)] does not cover secret sales or offers for sale." Manual of Patent Examining Procedures § 2152.02(d) (9th ed. 2014).

B. Facts and Procedural History

1. Petitioner is a small, family-owned pharmaceutical company based in Switzerland. Petitioner focuses on the research, development, and production of innovative products that improve cancer patients' health and quality of life. This case involves petitioner's flagship drug, Aloxi®, a groundbreaking treatment for chemotherapy-induced nausea and vomiting. Aloxi is by far petitioner's most successful product, accounting for the vast majority

of petitioner's revenues worldwide. Pet. Appl. for Stay of Mandate 17 (Jan. 18, 2018).

The active ingredient in Aloxi is palonosetron. Petitioner acquired the rights to palonosetron in 1998, after another company had abandoned efforts to develop it. In 2000, petitioner submitted confidential protocols for Phase III clinical trials to the Food and Drug Administration (FDA), in which it proposed to study two novel dosages of palonosetron, 0.25 mg and 0.75 mg, which were lower than those previously studied. Petitioner, which had never before sought approval for a drug in the United States, underestimated the costs of the development and approval process. As a result, the project was in danger of being terminated. Pet. App. 114a-115a.

To keep the project going, petitioner sought a business partner. In 2001, petitioner entered into a licensing agreement (and an accompanying purchase agreement) with MGI Pharma, a small Minnesota company. J.A. 52-212, 213-250. Under the agreements, MGI agreed to make upfront payments to petitioner to fund its development efforts, and also to pay future royalties if petitioner obtained FDA approval for a palonosetron product. J.A. 69-71, 80-87. In return, MGI received the rights to purchase from petitioner any approved palonosetron product and to distribute and market the product upon approval. J.A. 60, 219. The agreements described the potential products then being tested, including the claimed invention, a 0.25 mg formulation of palonosetron. J.A. 169, 248-249. The agreements bound MGI to keep confidential petitioner's proprietary knowledge related to the products, including the proposed formulation that constitutes the claimed invention; there is no dispute that MGI honored its confidentiality obligations. J.A. 107-109, 236-238.

Crucially, while the fact of petitioner's agreements with MGI was public knowledge, petitioner's claimed invention was never disclosed to the public (either by MGI or by anyone else) before petitioner began the patent-application process. While petitioner and MGI simultaneously announced the agreements in press releases, they did not provide information about petitioner's claimed formulation to the public. J.A. 251-254. And while MGI (as a public company) filed a Form 8-K with the Securities and Exchange Commission disclosing the fact of the agreements, it redacted the proposed formulation from the supporting documents. Pet. App. 22a-24a; J.A. 255-406.

In 2002, after the successful completion of clinical trials, petitioner submitted a confidential new-drug application to FDA for a 0.25 mg dose of palonosetron; FDA ultimately approved the application. In 2003, petitioner filed a provisional patent application covering the proposed formulation. Petitioner then filed a series of further applications claiming priority to the 2003 provisional application, culminating in a 2013 application that issued as U.S. Patent No. 8,598,219. That patent expires in 2024. By virtue of its effective application date, the patent is governed by the AIA. Pet. App. 19a, 25a.[1]

2. Respondents are Teva Pharmaceutical Industries, an Israeli company that is the world's largest generic drug manufacturer, and its American affiliate. In 2011, respondents filed an application seeking FDA approval to market a generic version of petitioner's 0.25 mg palono-

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[1] This case also involved three other patents governed by the pre-AIA version of the on-sale bar. Although petitioner disagrees with the Federal Circuit's determination that the pre-AIA on-sale bar invalidated those patents, see Pet. App. 27a-34a, petitioner has not sought review of that determination.

setron product. Respondents' application included a certification that petitioner's patents were invalid or would not be infringed by respondents' generic version. Under the Hatch-Waxman Act, which establishes the framework for certain pharmaceutical patent litigation, petitioner then filed a patent-infringement action against respondents in the United States District Court for the District of New Jersey. Pet. App. 26a.

After a bench trial, the district court held that petitioner's patent was valid and would be infringed by respondents' generic version of palonosetron. Pet. App. 53a-231a, 235a-241a. As is relevant here, the court rejected respondents' argument that petitioner's agreements with MGI invalidated the '219 patent under the AIA's on-sale bar. *Id.* at 164a. The court agreed with petitioner that, under the AIA, the on-sale bar applies only if a sale (or offer for sale) makes the claimed invention available to the public. *Ibid.*

The district court determined that, while the *fact* of the agreements between MGI and petitioner was public, the description of the claimed invention was redacted from the supporting documents in MGI's Form 8-K. Pet. App. 180a. Because there was no public disclosure of the *claimed invention* as a result of the agreements, the on-sale bar did not apply and the patent was valid. *Ibid.* The district court thus enjoined respondents from manufacturing or selling their generic version of Aloxi until the expiration of petitioner's patent in 2024. *Id.* at 234a.

3. Respondents appealed to the Federal Circuit. As is relevant here, respondents argued that, under the AIA, the catch-all phrase "or otherwise available to the public" does not inform the meaning of the preceding phrase "on sale," with the result that a sale (or offer for sale) need not make the claimed invention available to the public in order to trigger the on-sale bar. See Resp. C.A. Br. 42-61; Resp.

C.A. Reply Br. 15-31. Reaffirming the PTO's guidance to patent examiners, the United States agreed with petitioner, both in an amicus brief and at oral argument, that "[t]he plain text of section 102(a)(1) makes clear that only sales or offers for sale that make an invention 'available to the public' trigger the on-sale bar, and the purpose and structure of the AIA support that plain-text reading." Gov't C.A. Br. 4 (citation omitted).

4. The Federal Circuit reversed. Pet. App. 17a-52a. In its opinion, the court did not apply the traditional tools of statutory construction, nor did it come to grips with the parties' competing interpretations of the statutory language. Instead, after reciting the statutory text, the Federal Circuit proceeded to survey a selection of the floor statements of the AIA's sponsors. *Id.* at 36a-43a.

The Federal Circuit acknowledged that the floor statements addressing the on-sale bar suggested that a claimed invention must be "available to the public" in order to defeat patentability. Pet. App. 42a. But the court observed that the only cases the AIA's sponsors "explicitly referenced" by name involved the separate "public use" bar; the sponsors did not cite the earlier Federal Circuit decisions that had held so-called "secret sales" to be sufficient under the pre-AIA on-sale bar. *Id.* at 38a. Because "[t]he floor statements do not identify any *sale* cases that would be overturned by the amendments," the court reasoned, the AIA had no effect on the preexisting judicial interpretation of the on-sale bar. *Ibid.*

The Federal Circuit went on to explain that, "[e]ven if the floor statements were intended to overrule [the pre-AIA] secret or confidential sale cases," "that would have no effect here since those cases were concerned entirely with whether the *existence* of a sale or offer was public." Pet. App. 38a (emphasis added). The court stated that "[h]ere[] the existence of the sale—*i.e.*, the [agreement]

between [petitioner] and MGI—was publicly announced in MGI's 8-K filing to the SEC." *Ibid.* The court noted that "[t]here are no floor statements suggesting that the sale or offer documents must themselves publicly disclose the details of the claimed invention before the critical date." *Id.* at 43a. The court reiterated that, "[i]f Congress intended to work such a sweeping change to our on-sale bar jurisprudence," it would have done so "by clear language." *Ibid.* (citation omitted).

Based on that reasoning, the Federal Circuit held that, "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of the sale"—even where, as here, the counterparty was required to keep those details confidential (and the claimed invention, the specific "dosage level[]" of palonosetron, was concededly not disclosed to the public). Pet. App. 39a, 43a. Applying that holding, the court concluded that the sale to MGI triggered the AIA's on-sale bar. *Id.* at 43a, 52a.[2]

5. The Federal Circuit denied rehearing en banc. Pet. App. 2a.

Judge O'Malley, a member of the original panel, concurred in the denial of rehearing. Pet. App. 3a-16a. In the wake of the panel's failure to analyze the AIA's text in reaching its holding, Judge O'Malley proceeded to supply her own textual analysis. She reasoned that Congress did not intend to alter the meaning of the phrase "on sale" in the AIA because it retained that phrase without modification. *Id.* at 9a-10a. Seemingly for that reason, she concluded that "the AIA did not change longstanding precedent governing the on-sale bar." *Id.* at 3a-4a.

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[2] The Federal Circuit also determined that petitioner's invention was ready for patenting as of the relevant date. Pet. App. 43a-52a. Petitioner did not seek review of that determination.

Most significantly for present purposes, Judge O'Malley asserted that the new catch-all phrase "or otherwise available to the public" did not inform the meaning of "on sale." Pet. App. 8a-9a. A contrary interpretation, she reasoned, would "create redundancies" in Section 102(a)(1) and "equate 'on sale' with 'public use.'" *Id.* at 8a n.2, 10a. Judge O'Malley suggested that, in the phrase "otherwise available to the public," "'to the public' limits only 'otherwise available,'" not the preceding phrases "on sale" or "in public use." *Id.* at 9a. And she suggested that Section 102(b)(1)(B), which distinguishes between "disclosures" and "public[] disclos[ures]," supported her view that a sale need not make the claimed invention "available to the public." *Id.* at 10a-11a.

SUMMARY OF ARGUMENT

Under the plain text of the AIA, the sale of a claimed invention qualifies as prior art only if it makes the invention available to the public. The Federal Circuit made no effort to root its contrary interpretation in the statutory text. That interpretation was profoundly erroneous, and it requires reversal.

A. The plain text of the relevant provision, Section 102(a)(1), requires that a sale make the claimed invention available to the public. That provision enumerates two categories of patent-defeating prior art (claimed inventions that are "patented" and those that are "described in a printed publication") followed by a third category. The third category, in turn, sets out three additional ways of putting an invention into the public domain, with two enumerated subcategories (claimed inventions that are "in public use" and those that are "on sale") followed by a residual or catch-all subcategory (claimed inventions that are "otherwise available to the public").

Where a catch-all provision ("or otherwise available to the public") follows a list of more specific provisions, the items enumerated in the specific provisions must be read in light of the catch-all provision. That canon of statutory interpretation, which this Court has described as a "familiar" one, applies with particular force where, as here, Congress uses a term such as "otherwise" to link the catch-all provision to the preceding ones. Such a term reinforces the conclusion that the ensuing language in the catch-all provision sheds light on the meaning of the preceding provisions. The correct interpretation of the relevant language in Section 102(a)(1) is thus straightforward: a sale qualifies as patent-defeating prior art only if it makes the claimed invention "available to the public."

The broader structure of Section 102(a)(1) supports that interpretation. Under the *noscitur a sociis* canon, words in a statute are known by the company they keep. Here, the relevant characteristic—that the claimed invention be available to the public—is not only expressly identified in the catch-all subcategory, but also intrinsically shared by the two preceding enumerated categories ("patented" and "described in a printed publication"), and arguably also expressly shared by a preceding subcategory ("in public use"). Even apart from the catch-all provision, therefore, it would be natural to interpret the sole remaining subcategory ("on sale") to reach only sales that make the claimed inventions publicly available. This Court's decisions interpreting similar statutes strongly support the foregoing interpretation, and the Federal Circuit's contrary interpretation is textually unsustainable.

B. The legislative history supports the plain-text interpretation of the AIA. As early as 2005, patent-reform bills in the House and Senate proposed language requiring that prior art be available to the public. The Senate Judiciary Committee added the "otherwise available to

the public" language to the definition of prior art in 2007 for the specific purpose of making clear that so-called "secret sales" do not qualify as prior art. Congress retained similar language throughout the rest of the drafting process, and it included it verbatim in the final bill, which was enacted in 2011. And the AIA's named sponsors and other legislators repeatedly made clear that their understanding was the same as the Senate Judiciary Committee's: the additional language was intended to prevent secret sales or uses from qualifying as prior art going forward. The Federal Circuit's approach—discounting the foregoing history on the ground that Congress did not cite by name the earlier Federal Circuit decisions broadly construing the pre-AIA on-sale bar—is simply confounding.

C. The plain-text interpretation of the AIA is also consistent with the AIA's broader structure. In the AIA, Congress switched from a first-to-invent regime to a first-inventor-to-file regime for the stated purpose of harmonizing American patent law with the patent law of other countries. That change fundamentally altered the justification for the on-sale bar. Before the AIA, when patentability hinged on who was first to invent, an inventor could effectively extend the available patent term by selling the invention in secret. Under the AIA, however, an inventor who does not immediately file for a patent takes the risk that another inventor will file the first patent application and thus have priority. As a result, it is unnecessary for the on-sale bar to provide inventors with an additional incentive to enter the patent system promptly. All of the world's other major patent systems have first-to-file regimes that require a claimed invention to be available to the public in order to qualify as prior art. The Federal Circuit's interpretation would make American law an outlier, flouting Congress's statutory objective. It would also create serious incongruities with the rest of the AIA.

D. The Federal Circuit did not respond to petitioner's interpretation because it did not engage with the text of the AIA at all. Judge O'Malley, who was a member of the original panel, did advance a number of contrary textual arguments in her concurring opinion at the rehearing stage, largely tracking arguments respondents had made (and have continued to make before this Court). But none of those arguments can justify the Federal Circuit's interpretation. Those arguments either ignore the impact of Congress's changes to the on-sale bar in the AIA—including the crucial addition of the catch-all provision—or rest on mischaracterizations of petitioner's argument. Contrary to respondents' contention, Congress did not ratify the Federal Circuit's interpretation of the pre-AIA on-sale bar, and the plain-text interpretation does not create any problematic superfluity in the definition of prior art.

E. Finally, the plain-text interpretation promotes the policies underlying the patent system. The overarching goal of the patent system is to ensure that the public receives an appropriate benefit in exchange for the grant of a patent monopoly. Requiring that a sale make an invention available to the public in order to qualify as prior art is consistent with that goal. The Federal Circuit's interpretation sows substantial uncertainty, subjecting patentees to searching inquiries about their contacts and communications worldwide. And it has the perverse consequence of chilling innovation by small inventors such as petitioner, which often rely on partnerships to defray the costs and risks of developing new products. The Federal Circuit's interpretation of the AIA's on-sale bar is not just inconsistent with the statutory text and legislative history; it is also bad policy. It cannot be allowed to stand. This Court should reject the Federal Circuit's interpretation and reverse the judgment below.

ARGUMENT

UNDER THE AIA, A SALE QUALIFIES AS PRIOR ART ONLY IF IT MAKES THE CLAIMED INVENTION AVAILABLE TO THE PUBLIC

A. The Plain Text Of 35 U.S.C. 102(a)(1) Requires That A Sale Make The Claimed Invention Available To The Public

In the decision under review, the Federal Circuit ignored this Court's repeated admonition that the statutory-interpretation inquiry should begin with the text. See, *e.g.*, *Henson* v. *Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1721 (2017). And in this case, because the text answers the question presented, "that is also where the inquiry should end." *Puerto Rico* v. *Franklin California Tax-Free Trust*, 136 S. Ct. 1938, 1946 (2016) (internal quotation marks and citation omitted).

1. Section 102(a)(1) provides that an inventor is entitled to a patent unless "the claimed invention was patented, described in a printed publication, or in public use, on sale, or *otherwise available to the public* before the effective filing date of the claimed invention." 35 U.S.C. 102(a)(1) (emphasis added). The statute thus enumerates two categories of patent-defeating prior art—claimed inventions that are "patented" and those that are "described in a printed publication"—followed by a third category. That third category, in turn, sets out three additional ways of putting an invention into the public domain, with two enumerated subcategories (claimed inventions that are "in public use" and those that are "on sale") followed by a residual or catch-all subcategory (claimed inventions that are "otherwise available to the public").

Such catch-all provisions are a familiar feature of federal statutes. They allow Congress to "avoid the necessity of listing each matter * * * falling within" them, *CSX*

Transportation, Inc. v. *Alabama Department of Revenue*, 562 U.S. 277, 292 (2011), while still reaching "other devices not specifically enumerated but similar in purpose and effect" to the enumerated categories, *Federal Maritime Board* v. *Isbrandtsen Co.*, 356 U.S. 481, 492 (1958). And where, as here, a catch-all provision follows a list of more specific provisions, the items enumerated in the specific provisions "must be read in light of the final, comprehensive category." *Federal Maritime Commission* v. *Seatrain Lines, Inc.*, 411 U.S. 726, 734 (1973); see *Paroline* v. *United States*, 572 U.S. 434, 447 (2014).

That is especially true where Congress uses a term such as "otherwise" to link the catch-all provision to the preceding ones, as it did in Section 102(a)(1). This Court has long recognized the function that "otherwise" and analogous linking terms serve in lists of parallel words or phrases. See *United States* v. *Standard Brewery*, 251 U.S. 210, 218 (1920); *United States* v. *United Verde Copper Co.*, 196 U.S. 207, 213 (1905). Such terms, the Court has explained, confirm that the ensuing language will "relat[e] to and defin[e] the immediately preceding" language. *Standard Brewery*, 251 U.S. at 218. That makes good sense. "[O]therwise," after all, is an adverb that means "in a different way or manner." *Merriam-Webster's Collegiate Dictionary* 879 (11th ed. 2009). The use of "otherwise" thus signals that the language it accompanies necessarily connects to, and informs the meaning of, the language that precedes it.

Here, the correct interpretation of the relevant language in Section 102(a)(1) is straightforward. The catch-all subcategory "or otherwise available to the public" sheds light on the meaning of the preceding subcategories by identifying a key characteristic that those subcategories should be understood to share. When "read in light of the final, comprehensive category," therefore, "on sale"

naturally refers to a sale (or offer for sale) that makes the claimed invention publicly available. *Seatrain Lines*, 411 U.S. at 734.

The broader structure of Section 102(a)(1) supports that interpretation. Under the venerable *noscitur a sociis* canon of statutory interpretation, words in a statute are "known by the company [they] keep[]." See, *e.g.*, *Gustafson* v. *Alloyd Co.*, 513 U.S. 561, 575 (1995) (interpreting "communication[s]" to refer only to public communications because the term appeared in a list referring to "documents of wide dissemination"). That familiar interpretive principle prevents courts from "ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." *Ibid.* (internal quotation marks and citation omitted).

The *noscitur a sociis* canon confirms petitioner's interpretation of Section 102(a)(1). The relevant characteristic—that the claimed invention be "available to the public"—is not only expressly identified in the catch-all subcategory, but also intrinsically shared by the two preceding enumerated categories: *i.e.*, claimed inventions that are "patented" or "described in a printed publication." It is arguably also expressly shared by a preceding enumerated subcategory: *i.e.*, claimed inventions that are "in public use." See Pet. App. 9a n.2 (O'Malley, J., concurring in the denial of rehearing) (stating that "public use," like "patented" and "printed publication," "recites a disclosure that is necessarily public"); Br. in Opp. 3, 21-23 (same); but see p. 43, *infra* (discussing Federal Circuit cases construing the pre-AIA "public use" subcategory more broadly). Even apart from the catch-all provision, therefore, it would be natural to interpret the sole remaining subcategory—claimed inventions that are "on sale"—to reach only sales that make the claimed inventions avail-

able to the public. See, *e.g.*, *Gustafson*, 513 U.S. at 575; *Seatrain Lines*, 411 U.S. at 736. Put simply, Section 102 (a)(1) seeks to capture all of the ways in which an inventor can put an invention into the public domain.

2. This Court's decisions in *Seatrain Lines* and *Paroline*, *supra*, strongly support the foregoing interpretation. *Seatrain Lines* involved Section 15 of the Shipping Act of 1916, which required covered parties to report certain agreements to the Federal Maritime Commission and gave the Commission the authority to approve or reject the agreements. See 411 U.S. at 726-727. In *Seatrain Lines*, one maritime carrier contracted to acquire the assets of another. See *id.* at 729. The parties reported their agreement to the Commission under the Shipping Act, and the Commission approved the agreement. See *id.* at 730. The effect of that approval was to remove the contract from scrutiny under the federal antitrust laws. See *id.* at 728. Seatrain Lines, a competitor of the now-combined carrier, objected. See *id.* at 729-731.

The relevant statutory provision enumerated six categories of agreements the Commission could approve; it then included a catch-all category for agreements "in any manner providing for an exclusive, preferential, or cooperative working arrangement." 411 U.S. at 732. There was no question that the catch-all category, along with five of the six enumerated categories, was "expressly limited to ongoing arrangements in which both parties undertake continuing responsibilities." *Id.* at 733-734. The remaining enumerated category required parties to report agreements "controlling, regulating, preventing, or destroying competition." *Id.* at 732. Seatrain Lines argued that the Commission lacked the authority to approve the agreement because the Commission's jurisdiction extended only to agreements that created ongoing obligations and not to one-time agreements. See *id.* at 732-733.

In response, the Commission argued that the reference to "destroying competition" in the relevant category demonstrated that the provision "was intended to cover one-time, discrete transactions." *Id.* at 733-734.

The Court agreed with Seatrain Lines and held that the Commission lacked the authority to approve the agreement. See 411 U.S. at 736, 745. As is relevant here, the Court reasoned that each enumerated category "must be read in light of the final, comprehensive category," which was "clearly meant as a catchall provision, intended * * * to summarize the type of agreements covered." *Id.* at 734 (alteration in original; internal quotation marks and citation omitted). The Court explained that it was a "familiar canon of statutory construction" that "such clauses are to be read as bringing within a statute categories similar in type to those specifically enumerated." *Ibid.* "Since the summary provision is explicitly limited to 'working arrangement(s),'" the Court concluded, "it is reasonable to conclude that Congress intended this limitation to apply to the specifically enumerated categories as well." *Ibid.* (alteration in original; footnote omitted).

This Court's recent decision in *Paroline* is of a piece. There, the Court construed a statute providing restitution for losses suffered by victims of child pornography. See 572 U.S. at 443. The relevant provision enumerated five categories of covered losses—"medical services," "physical and occupational therapy," "transportation, temporary housing, and child care," "lost income," and "attorney's fees and costs"—followed by a "final catchall category for 'any other losses suffered by the victim as a proximate result of the offense.'" *Id.* at 446 (quoting 18 U.S.C. 2259(b)(3)(F)). The question presented was whether a victim had to make a showing that the claimed loss was a "proximate result of the offense" before recovering under

the five enumerated categories, even though none of those categories included a causation requirement.

The Court answered in the affirmative. Quoting from *Seatrain Lines*, the Court reiterated that it is a "familiar canon of statutory construction" that enumerated provisions in a statute must be read in light of a catch-all provision that follows them. 572 U.S. at 447 (quoting 411 U.S. at 734). Because the statute defined a "broad, final category of 'other losses suffered * * * as a proximate result of the offense,'" the Court reasoned, "[t]hat category is most naturally understood as a summary of the type of losses covered—*i.e.*, losses suffered as a proximate result of the offense." *Ibid.* (alteration in original). The Court concluded that, even though it appeared only in the catch-all provision, "the proximate-cause requirement applies to all the losses described in [the statute]." *Id.* at 448.

The logic of *Seatrain Lines* and *Paroline* resolves this case. Like the statutes at issue in *Seatrain Lines* and *Paroline*, Section 102(a)(1) contains a list of enumerated categories, followed by a catch-all category. The catch-all provision in Section 102(a)(1) expressly requires that the claimed invention be "otherwise available to the public." In addition, as with the statute in *Seatrain Lanes*, most if not all of the enumerated categories in Section 102(a)(1) intrinsically share the characteristic that is expressly set out in the catch-all category, confirming that the enumerated category of "on sale" inventions should also share that characteristic. See also *Gustafson*, 513 U.S. at 575. In short, the catch-all category "is most naturally understood as a summary" of what constitutes patent-defeating prior art: any action that puts a claimed invention into the public domain. *Paroline*, 572 U.S. at 447.

If anything, this is an easier case than *Seatrain Lines* or *Paroline*. In *Seatrain Lines*, the catch-all provision at

issue required the reporting of an agreement "in any manner providing for an exclusive, preferential, or cooperative working arrangement." 411 U.S. at 732. The catch-all provision thus did not contain a connective term such as "other" or "otherwise," and the shared characteristic—the existence of an ongoing obligation—was implicit. *Id.* at 734. Here, by contrast, the catch-all provision is introduced by "otherwise," and the shared characteristic—the public availability of the claimed invention—is explicit. 35 U.S.C. 102(a)(1). And in *Paroline*, *none* of the enumerated categories of damages intrinsically shared the characteristic that the catch-all provision described—proximate causation of the loss. See 572 U.S. at 446. Here (as in *Seatrain Lines*), by contrast, most if not all of the other enumerated categories do so. See 35 U.S.C. 102(a)(1); *Seatrain Lines*, 411 U.S. at 733-734; see also, *e.g.*, *Gustafson*, 513 U.S. at 575.

Seatrain Lines and *Paroline*, in other words, presented complications that this case does not. In each instance, however, the Court applied the "familiar canon of statutory construction" for catch-all provisions and determined that the catch-all provision at issue established a shared characteristic for preceding parallel provisions. *Paroline*, 572 U.S. at 447 (quoting *Seatrain Lines*, 411 U.S. at 734). The same conclusion follows *a fortiori* here: in light of the catch-all provision that Congress added in the AIA, a sale qualifies as patent-defeating prior art only if it makes the claimed invention "available to the public." 35 U.S.C. 102(a)(1).[3]

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[3] Respondents have forfeited any alternative argument that, even if public availability is legally required, the sale to MGI (or the subsequent disclosure of the sale) somehow made the claimed invention "available to the public" on the facts of this case. See Gov't C.A. Br. 2-3 (noting that respondents "[did] not dispute" that issue). That was

B. The Legislative History Of The AIA Supports The Plain-Text Interpretation

Because the plain text of Section 102(a)(1) resolves the question presented, "that is * * * where the inquiry should end." *Franklin California Tax-Free Trust*, 136 S. Ct. at 1946 (internal quotation marks and citation omitted). To the extent the Court wishes to consider it, however, "the legislative history * * * confirms that Congress intended the statute to mean exactly what its plain language says." *Griffin* v. *Oceanic Contractors, Inc.*, 458 U.S. 564, 574 (1982). The legislators who enacted the AIA were perfectly clear about what they intended to do (impose a public-availability requirement) and how they intended to do it (by adding the catch-all provision). If there were any lingering doubt about the meaning of Section 102(a)(1)—and there should be none—the legislative history puts the matter beyond all reasonable dispute.

1. As early as 2005, patent reform bills in the House and Senate proposed language requiring that prior art be publicly available. See H.R. 2795, 109th Cong. (2005) (proposing that new Section 102(a)(1) prohibit the issuance of a patent when "the claimed invention was patented, described in a printed publication, *or otherwise publicly*

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a prudent strategic decision, because there is no colorable argument to the contrary. The relevant inquiry is whether the "subject matter defined by a claim in a patent or an application for a patent"—here, the drug dosage and formulation—was available to the public. 35 U.S.C. 100(j). While the *fact* of the sale to MGI was public, the "details of the formulation" "w[ere not] described publicly," as respondents conceded at oral argument before the Federal Circuit. C.A. Oral Arg. at 5:30-5:38. Nor was the claimed invention sold to the public (or otherwise placed in the public domain) until long after the effective filing date of the patent application. Should this Court agree that the Federal Circuit misinterpreted Section 102(a)(1) by not requiring public availability, therefore, it must reverse the judgment below.

known" before the relevant date (emphasis added)); S. 3818, 109th Cong. (2006) (same).

The current statutory text first appeared in 2007. At that time, parallel patent reform bills were making their way through the House and the Senate. Neither bill initially contained the "otherwise available to the public" catch-all provision; each provided only that "[a] patent for a claimed invention may not be obtained if * * * the claimed invention was patented, described in a printed publication, in public use, or on sale." H.R. 1908, 110th Cong. (2007); S. 1145, 110th Cong. (2007). Shortly thereafter, however, the Senate Judiciary Committee amended its bill to add the "otherwise available to the public" language that Section 102(a)(1) now contains, and the accompanying committee report explained why:

> This Manager's Amendment also added the phrase "otherwise available to the public" to [Section] 102 to make clear that *secret collaborative agreements, which are not available to the public, are not prior art.*

S. Rep. No. 259, 110th Cong., 2d Sess. 39 (2008) (emphasis added). The report elsewhere stated that the language was added to "emphasize the fact that [prior art] must be publicly available." *Id.* at 9.

With minor variation, the catch-all provision became a fixture of subsequent patent reform bills in both houses in the next two Congresses, culminating in the enactment of the AIA in 2011. See Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 472 (2012). When it considered the bill that ultimately became the AIA, the House Judiciary Committee echoed the explanation that the catch-all provision was intended to "emphasize the fact that [prior art] must be publicly accessible." H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. I, at 42-43 & n.20 (2011).

The AIA's sponsors confirmed that understanding during the bill's pendency. In a floor speech just before the Senate's vote on the bill, Senator Kyl noted that "[t]he words 'otherwise available to the public' were added to section 102(a)(1) during * * * mark up of [a predecessor] bill." 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011). Directly addressing the question presented here, he explained that "[t]he word 'otherwise' makes clear that the preceding clauses describe things that are of the same quality or nature as the final clause—that is, although different categories of prior art are listed, all of them are limited to that which makes the invention 'available to the public.'" *Ibid.*

What is more, Senator Kyl specified that "sales" were among the categories of prior art whose meaning the AIA clarified:

> Moreover, the fact that the clause "or otherwise available to the public" is set off from its preceding clauses by a comma confirms that it applies to both "public use" and "on sale." * * * Thus new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated by the bill—an understanding on which the remainder of the bill is predicated.

157 Cong. Rec. S1370. In short, new Section 102(a)(1) was intended to "limit[] *all* non-patent prior art to that which is available to the public." *Ibid.* (emphasis added).

Senator Kyl recognized the concern that a so-called "secret sale" could be viewed as an effort to commercialize an invention before patenting. 157 Cong. Rec. S1371. But Senator Kyl responded that there was "no reason to fear 'commercialization' that merely consists of a secret sale or offer for sale but that does not operate to disclose the invention to the public." *Ibid.* That was because the AIA's new first-inventor-to-file regime would "provide[] ample

incentive for an inventor to enter the patent system promptly," and there was no need for an expansive definition of prior art to create that incentive. *Ibid.* New Section 102(a)(1) thus "eliminates the use of the definition of prior art to pursue varied goals such as encouraging prompt filing or limiting commercialization" and instead "serve[s] only one purpose": to "prevent the withdrawal by an inventor of that which was already in the possession of the public." *Ibid.* (internal quotation marks and citation omitted); see pp. 31-32, *infra*.

Senator Kyl added that there were other good reasons to narrow the definition of prior art to exclude such "secret sales." 157 Cong. Rec. S1371. As he explained, the pre-AIA definition of prior art, as construed by the Federal Circuit, created "traps for unwary inventors" and "impose[d] extreme results to no real purpose." *Ibid.* Litigating the issue of whether a secret sale constituted prior art served only to "create heavy discovery costs in every patent case, and to punish small inventors who are unaware of the pitfalls of the current definition of prior art." *Ibid.*

Other sponsors of the AIA, including the two eponymous sponsors, made similar points. The AIA's lead sponsor in the Senate, Senator Leahy, made clear that Section 102(a)(1) was intended to "do away with precedent under current law that private offers for sale or private uses of secret processes * * * may be deemed patent-defeating prior art." 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011).[4] And the AIA's lead sponsor in the House, Representative Lamar Smith, echoed Senator Leahy's understanding. 157 Cong. Rec. H4429 (daily ed. June 22, 2011).

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[4] Although Senator Leahy's remarks were published after the Senate's initial vote, they preceded the final vote and were cited in the House Judiciary Committee's report. See H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. I, at 43 n. 20 (2011).

He explained that, "contrary to current precedent, in order to trigger the bar in the new [Section] 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date." *Ibid.*

2. In an apparent return to the discredited methodology of *Church of the Holy Trinity* v. *United States*, 143 U.S. 457 (1892), the Federal Circuit resorted immediately to the legislative history in its opinion. Yet it cited no legislative history affirmatively supporting its interpretation. Instead, it merely sought to minimize the significance of the foregoing legislative history, suggesting that Congress could not have intended to modify the operation of the on-sale bar because it did not cite by name the Federal Circuit's decisions construing the pre-AIA on-sale bar. See, *e.g.*, Pet. App. 38a, 42a-43a.

That contention is as astounding as it is self-aggrandizing. This Court has never imposed such a legislative-history clear-statement rule on Congress even with regard to its own decisions, never mind the decisions of the Federal Circuit. It would be one thing if Congress left the statutory language untouched. See pp. 39-40, *infra* (discussing the doctrine of congressional ratification). Here, however, Congress expressly modified the relevant statutory provision by including the catch-all provision. And the AIA's sponsors made clear that, in so doing, Congress intended to "limit[] *all* non-patent prior art to that which is available to the public." 157 Cong. Rec. S1370 (statement of Sen. Kyl) (emphasis added). In order to effect that change, the AIA's sponsors were hardly obligated to tip their hat to the Federal Circuit's decisions construing the preexisting statutory language.

Perhaps belatedly recognizing the absurdity of the position taken by the original panel, Judge O'Malley took a different tack in her concurring opinion at the rehearing

stage. She noted that Congress had considered but rejected bills that eliminated sales altogether from the definition of prior art. See Pet. App. 11a-12a. But that is of no moment, because petitioner is not arguing that the AIA eliminated the on-sale bar; the question presented here is *which* sales trigger the AIA's on-sale bar.

In that regard, the drafting history strongly supports petitioner's interpretation. It shows that, starting in 2005, Congress consistently included a public-availability requirement of one kind or another in the proposed definition of prior art. See pp. 25-26, *supra*. And to the extent Congress ultimately decided to retain "on sale" as a discrete category of prior art, that decision makes eminent sense, because it preserves the substantial body of law on other aspects of the on-sale bar while clarifying that a sale must make the claimed invention publicly available in order to qualify as prior art. See Markup of H.R. No. 1249, House Committee on the Judiciary, at 101 (Apr. 14, 2011); see also pp. 40-42, *infra*.

In short, while the Federal Circuit relied exclusively on the legislative history, that history confirms what the plain text of Section 102(a)(1) already unambiguously provides: a sale qualifies as prior art only if it makes the claimed invention available to the public. The Federal Circuit's contrary interpretation is unsustainable.

C. The Structure Of The AIA Further Supports The Plain-Text Interpretation

The foregoing interpretation of Section 102(a)(1)—under which a sale must make a claimed invention publicly available in order to qualify as prior art—is also consistent with the broader structure of the new and fundamentally different patent system Congress adopted in the AIA. The Federal Circuit's interpretation, by contrast,

would create serious incongruities with the rest of the statute.

1. a. Congress's stated objective in enacting the AIA was to "improve the United States patent system and promote harmonization of the United States patent system" with the patent systems of other countries. Pub. L. No. 112-29, § 3(p), 125 Stat. 293 (2011). Congress achieved that objective primarily by changing the rules for determining priority—that is, who among competing inventors has the right to patent a claimed invention. Before the AIA, the United States had a first-to-invent regime: the first inventor was entitled to a patent, regardless of whether the inventor was the first to file a patent application that covered the claimed invention. See 35 U.S.C. 102(a) (2006).

In the AIA, the Congress switched to a first-to-file regime, thus harmonizing American law with the laws of most other major nations (including all of the other "IP5" patent systems—Europe, China, Korea, and Japan). See 35 U.S.C. 102(a)(1).[5] Under that system, the first inventor to file a patent application is entitled to a patent, even if another inventor came up with and pursued the idea first. The purpose and effect of that change was to "encourage[] the prompt filing of patent applications" by focusing the patentability inquiry solely on the date of the earliest relevant application, rather than the date of the invention. S. Rep. No. 259, 110th Cong., 2d Sess. 7 (2008).

A critical component of the switch from a first-to-invent system to a first-inventor-to-file system was Congress's new definition of prior art. Before the AIA, when patentability hinged on who was the first inventor, patent

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[5] The "IP5" patent systems are the world's largest, handling approximately 80% of patent applications worldwide. See Patent and Trademark Office, *IP5 Statistics Report, 2016 Edition* 41, 87 (Nov. 2017) <tinyurl.com/ip5statistics>.

law recognized certain categories of "secret" prior art. Most obviously, a patent could not issue if another inventor had developed the invention earlier, even if the first inventor had not disclosed the invention to the public. See 35 U.S.C. 102(g) (2006); *OddzOn Products, Inc.* v. *Just Toys, Inc.*, 122 F.3d 1396, 1401-1404 (Fed. Cir. 1997). Congress naturally eliminated that rule, and other categories of "secret" prior art, as part of the move to a first-inventor-to-file system. See Manual of Patent Examining Procedures § 2151 (9th ed. 2014).

Before the AIA, the Federal Circuit had similarly construed the on-sale bar to reach so-called "secret sales" (*i.e.*, sales that did not disclose inventions to the public). See p. 41, *infra*. Whatever the propriety of those decisions, it makes sense that Congress would have wanted the post-AIA on-sale bar to apply only to sales that put the claimed inventions into the public domain. In a first-to-invent system, an inventor could effectively extend the available patent term by selling the invention in secret. If a competitor sought to patent the invention, the original inventor could then surface, file a patent application, and claim priority. To the extent it reached "secret sales," the pre-AIA on-sale bar gave inventors an additional incentive to enter the patent system promptly.

That incentive is no longer necessary in a first-inventor-to-file system. An inventor who does not immediately file a patent application runs the risk that a rival inventor will get to the Patent Office first; the AIA thus already gives the inventor a substantial incentive to file an application promptly. As a result, it is perfectly logical that the Congress that adopted the first-inventor-to-file system would have intended the on-sale bar to reach only sales that make claimed inventions publicly available.

b. Consistent with the foregoing rationale, all of the other "IP5" patent systems—which have long since

adopted the first-inventor-to-file method—require a claimed invention to be available to the public in order to qualify as prior art.

In Europe, for example, prior art "shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application." European Patent Convention, art. 54(2) (16th ed. June 2016) <tinyurl.com/europepriorart>. In China, prior art "mean[s] the technologies known to the public both domestically and abroad before the date of application." Patent Law of the People's Republic of China, art. 22 (Dec. 27, 2008) <tinyurl.com/chinapriorart>. In Korea, "[i]f an invention is disclosed to a person who is obligated to keep it confidential, it is not public knowledge" and thus does not qualify as prior art. Korean Intellectual Property Office, *Understanding the Patent Act of the Republic of Korea* 49 (2017) <tinyurl.com/repkoreapriorart>. And in Japan, "'[p]ublicly known prior art' means prior art which has become known to anyone as an art without an obligation of secrecy." Examination Guidelines for Patent and Utility Model in Japan, pt. III, ch. 2, § 3-3.1.3 (June 2018) <tinyurl.com/japanpriorart>.

The Federal Circuit's interpretation would thus make the United States the only major patent system to treat so-called "secret sales" as prior art. That, in turn, would flout Congress's broader objective in the AIA of "promot[ing] harmonization of the United States patent systems with the patent systems commonly used" around the world. Pub. L. No. 112-29, § 3(p), 125 Stat. 293. And it would ignore the broader changes that Congress made to the patent system, also for the purpose of promoting harmonization, when it enacted the AIA.

2. a. The Federal Circuit's interpretation would create other serious anomalies in the AIA. Consider, for example, the effect of the Federal Circuit's view on the scope of the on-sale bar. If a sale could trigger the AIA's on-sale bar without making the claimed invention available to the public, the practical effect of the AIA would have been to broaden the on-sale bar dramatically. That is because the AIA eliminated the preexisting territorial limitation on the on-sale bar: namely, that an invention must have been on sale (or in public use) "in this country" in order to qualify as prior art. 35 U.S.C. 102(b) (2006); see 35 U.S.C. 102(a)(1). Under the Federal Circuit's interpretation, the on-sale bar would apply to a sale occurring anywhere in the world, regardless of whether it discloses the claimed invention to the public.

There is no indication that Congress intended to expand the scope of the on-sale bar so radically. Quite to the contrary, Congress's decision to eliminate the territorial limitation on the on-sale bar seems to have gone hand in hand with its clarification that an invalidating sale must make the claimed invention available to the public. As Senator Kyl explained in his floor statement, "a general public availability standard is a necessary accompaniment to this bill's elimination of geographic restrictions on the definition of prior art." 157 Cong. Rec. S1371. The reason is that a public sale—even in a foreign country—"is relatively hard to falsify." *Ibid.* But if even a "secret offer for sale" in a foreign country were sufficient, it "would place U.S. inventors at grave risk of having their inventions stolen through fraud." *Ibid.*

b. The Federal Circuit's interpretation would also create significant tension with the new post-grant-review procedure that Congress adopted in the AIA. See 35 U.S.C. 321-329. Congress envisioned a "more efficient

system for challenging patents that should not have issued." H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. I, at 39-40 (2011). The post-grant-review procedure, one of several administrative-review mechanisms for issued patent claims, permits patentability challenges to patents that are subject to the AIA's definition of prior art. See 35 U.S.C. 321 note (1)(A). Consistent with Congress's desire to create an efficient alternative to litigation in federal court, however, the post-grant-review procedure permits only limited discovery, which is expected to last no more than a year after institution. See 35 U.S.C. 326(a)(5), (6), (11).

The post-grant-review procedure is thus not designed to handle invalidity challenges based on sales in which the claimed invention or the entire transaction is kept secret, because proving the existence of such sales would likely require onerous discovery. As Senator Kyl explained, the post-grant-review process "would be utterly unmanageable if the validity of all patents subject to review under the new system continued to depend on discovery-intensive searches for secret offers for sale and non-disclosing uses by third parties." 157 Cong. Rec. S1371. That is plainly not what Congress intended, and it further underscores why this Court should reject the Federal Circuit's interpretation.

D. The Arguments In Support Of The Federal Circuit's Interpretation Are Invalid

Remarkably, in the decision below, the Federal Circuit did not engage with the text of Section 102(a)(1) at all. In her concurring opinion at the rehearing stage, however, Judge O'Malley belatedly advanced a series of textual arguments in support of the court's ultimate conclusion that the on-sale bar was applicable, if not its precise

holding that the mere disclosure of the fact of a sale triggers the on-sale bar. See Pet. App. 3a-16a. Judge O'Malley's opinion, in turn, largely tracked arguments respondents had presented in the court of appeals and have continued to press before this Court. See *id.* at 8a-11a; Br. in Opp. 19-27.

As we will now explain, none of those textual arguments can justify the Federal Circuit's text-free interpretation of Section 102(a)(1). Those arguments misapply this Court's statutory-interpretation jurisprudence. They manufacture illusory anomalies that the plain-text interpretation would supposedly create. And they import irrelevant pre-AIA authorities into the analysis of the AIA's on-sale bar. This Court should adopt the plain-text interpretation of Section 102(a)(1) and reject the Federal Circuit's.

1. Respondents first contend that the catch-all phrase "otherwise available to the public" merely reaches an additional category of disclosures not covered by the enumerated categories in Section 102(a)(1) and thus does not inform the meaning of those categories. See Br. in Opp. 19-20; see also Pet. App. 9a (O'Malley, J., concurring in the denial of rehearing).

Respondents' conclusion does not follow from their premise. It is of course true that a catch-all phrase such as "otherwise available to the public" can encompass items "not specifically enumerated" in a statute. *Isbrandtsen*, 356 U.S. at 492; see Br. in Opp. 20 (citing, as examples, oral and video disclosures of claimed inventions). After all, a catch-all provision certainly "catches" things that the more specific preceding provisions do not. See, *e.g.*, *CSX Transportation*, 562 U.S. at 292.

But the question presented here is not whether some type of disclosure that does *not* fall within one of the enu-

merated categories nevertheless qualifies as prior art because it makes the claimed invention "available to the public." Instead, the question presented involves the interpretation of the enumerated categories themselves—specifically, whether a disclosure that does not make a claimed invention "available to the public" can nevertheless qualify as prior art. The answer to that question is no, for the reasons stated above: a catch-all provision states a shared characteristic that informs the meaning of a preceding parallel provision, especially where the characteristic is intrinsically shared by other preceding provisions as well. See pp. 18-24, *supra*.

The essence of respondents' contention is that "otherwise available to the public" is not really a catch-all provision at all; instead, it defines an independent category, with the result that the preceding categories should be construed in isolation. But that ignores the word "otherwise," which explicitly links the catch-all provision (and its shared characteristic) to the preceding provisions. See, *e.g.*, *Paroline*, 572 U.S. at 447; *Standard Brewery*, 251 U.S. at 218; *United Verde Copper*, 196 U.S. at 213. Respondents' interpretation would leave "otherwise" with no function, violating the rule against superfluity. See, *e.g.*, *Hibbs* v. *Winn*, 542 U.S. 88, 101 (2004); *Standard Brewery*, 251 U.S. at 218. In light of Congress's use of "otherwise," there can be no serious debate that "otherwise available to the public" is a catch-all provision—and, consistent with this Court's cases construing other catch-all provisions, it sheds light on the meaning of the provisions that precede it. See *Paroline*, 572 U.S. at 447; *Seatrain Lines*, 411 U.S. at 734.

2. In a similar vein, respondents contend that, under the rule of the last antecedent, the phrase "to the public" only modifies the term "available" and thus does not inform the meaning of the other subcategories of Section

102(a)(1). See Br. in Opp. 23-25; see also Pet. App. 9a (O'Malley, J., concurring in the denial of rehearing).

Again, respondents' conclusion does not follow from their premise. The rule of the last antecedent provides that "a limiting clause or phrase * * * should ordinarily be read as modifying only the noun or phrase that it immediately follows." *Barnhart* v. *Thomas*, 540 U.S. 20, 26 (2003). The question in this case, however, is not whether "to the public," as a prepositional phrase, modifies (and only modifies) "otherwise available"; it plainly does.[6] Instead, the relevant question is whether the adjectival phrase "otherwise available to the public"—as a whole—informs the meaning of the *parallel* adjectival phrases that precede it. For the reasons stated above, the answer to that question is plainly yes.

Indeed, this Court rejected a similar (and similarly off-key) invocation of the rule of the last antecedent in *Paroline*. There, the victim contended that, in the catch-all category at issue, the phrase "suffered by the victim as a proximate result of the offense" only modified the phrase "any other losses" and thus did not inform the meaning of the preceding enumerated categories of damages. See 572 U.S. at 446. Yet the Court rejected that argument, reasoning that "[o]ther canons of statutory construction * * * work against the reading the victim suggests." *Id.* at 447. So too here: the interpretive question in this case is controlled by the "familiar canon of statutory construction" that enumerated provisions in a statute must be read in light of a catch-all provision that follows them. *Ibid.*; *Seatrain Lines*, 411 U.S. at 734.

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[6] Strictly speaking, "otherwise available" is not even an antecedent, because an antecedent presupposes the existence of a relative or other pronoun. Take the phrase "the spy who came in from the cold"; "the spy" is the antecedent, and "who" the relative pronoun.

Once again, respondents' approach effectively reads the word "otherwise" out of the statute. If respondents' invocation of the rule of the last antecedent were accepted, it would leave "otherwise" with no function, because the catch-all provision would shed no light on the meaning of the preceding provisions. This Court has previously refused to create superfluity by applying the rule of the last antecedent. See *United States* v. *Hayes*, 555 U.S. 415, 425-426 (2009). The only way to give "operative meaning" to "otherwise" is to read "otherwise available to the public" as qualifying the preceding categories. *Ibid.* In any event, in light of the structure of Section 102(a)(1) more generally and the catch-all provision specifically, the rule of the last antecedent simply does not apply here.

3. Respondents further contend that Congress ratified the Federal Circuit's interpretation of the pre-AIA on-sale bar by retaining the phrase "on sale" in Section 102(a)(1). See Br. in Opp. 20-21; see also Pet. App. 9a-10a (O'Malley, J., concurring in the denial of rehearing).

The doctrine of congressional ratification is likewise inapplicable. As a general matter, the Court presumes that Congress was "aware of an administrative or judicial interpretation of a statute," and intended to "adopt that interpretation when it re-enacts a statute." *Lorillard* v. *Pons*, 434 U.S. 575, 580 (1978). But "the doctrine of congressional ratification applies only when Congress reenacts a statute without relevant change." *Holder* v. *Martinez Gutierrez*, 566 U.S. 583, 593 (2012).

The AIA does not satisfy that requirement. Most obviously, in the AIA, Congress did not merely retain the phrase "on sale"; it added the catch-all phrase "or otherwise available to the public." 35 U.S.C. 102(a)(1). Congress also eliminated the pre-AIA requirement that an invalidating public use or sale occur "in this country," and it

replaced the term "invention" with the defined phrase "claimed invention." 35 U.S.C. 100(j). And, of course, Congress fundamentally changed the nature of the American patent system by shifting from a first-to-invent system to a first-inventor-to-file system, thus eliminating one possible rationale for the on-sale bar. See pp. 31-32, *supra*. Collectively, those changes foreclose reliance on the congressional-ratification doctrine.

Indeed, by retaining the phrase "on sale" but adding the catch-all phrase "or otherwise available to the public," Congress chose a sensible way of amending the statute to achieve its desired objective. As respondents correctly note, there was a substantial body of pre-AIA law addressing various aspects of the on-sale bar. See Br. in Opp. 20-21; see also Pet. App. 14a-16a & n.5 (O'Malley, J., concurring in the denial of rehearing). Much of that law had nothing to do with the public availability of a claimed invention.

For example, this Court established a two-prong test for determining whether an invention is "on sale," considering (1) whether the product was the subject of a commercial offer of sale and (2) whether the invention is ready for patenting. See *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55, 67 (1998). The Federal Circuit has elaborated on that test in a series of cases on what constitutes a commercial sale, see, *e.g.*, *Medicines Co.* v. *Hospira, Inc.*, 827 F.3d 1363, 1374-1379 (Fed. Cir. 2016) (en banc), and when a claimed invention was ready for patenting, see, *e.g.*, *August Technology Corp.* v. *Camtek, Ltd.*, 655 F.3d 1278, 1288-1290 (Fed. Cir. 2011). None of those authorities bears on the question presented here: namely, whether a

claimed invention must be made available to the public in order to qualify as prior art under the AIA.[7]

Before the AIA, however, the Federal Circuit had also applied the on-sale bar even if an inventor's sale of an invention to another party did not disclose the invention to the public. For example, in *Special Devices, Inc.* v. *OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), the court held that a patentee's contract with a supplier to manufacture the product embodying an invention constituted a disqualifying "sale," even though the production activity and the invention remained secret. See *id.* at 1357. Similarly, in *In re Caveney*, 761 F.2d 671 (Fed. Cir. 1985), the court upheld the application of the on-sale bar to an offer to sell the claimed invention to a single entity, even though the counterparty "kept the claimed invention secret from the purchasing public" and the sale activity was "kept secret from the trade." *Id.* at 674-675.

The inclusion of the catch-all phrase "or otherwise available to the public" clarifies that the AIA on-sale bar should be construed differently from the pre-AIA on-sale bar in those cases; under the AIA, a sale must make a claimed invention available to the public in order to trigger the on-sale bar. See pp. 18-24, *supra*.[8] At the same

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[7] The Federal Circuit's cases on whether a commercial sale has taken place consider whether the fact of the sale has been disclosed as one factor in the analysis. See, *e.g.*, *Medicines*, 827 F.3d at 1376. In attaching significance to the disclosure of the *fact* of the sale to MGI, the Federal Circuit appears to have relied on those cases. See, *e.g.*, Pet. App. 35a-36a, 38a-39a; see also *id.* at 4a-7a (O'Malley, J., concurring in the denial of rehearing). But those cases are inapposite here, because the question before this Court is not whether a sale took place, but instead whether the sale triggered the AIA on-sale bar.

[8] This case presents no occasion for the Court to consider whether those Federal Circuit cases correctly construed the pre-AIA version of the on-sale bar. See p. 10 n.1, *supra*.

time, the retention of the phrase "on sale" avoids "throw-[ing] the baby out with the bath water," *Federal Trade Commission* v. *Actavis*, 570 U.S. 136, 157 (2013), because it preserves the substantial body of law on other aspects of the on-sale bar. Far from ratifying *every* aspect of preexisting law, Congress acted with precision in order to modify the aspect of preexisting law with which it disagreed.

4. Respondents contend that petitioner's interpretation of Section 102(a)(1) would create superfluity in various respects. See Br. in Opp. 23-27; see also Pet. App. 10a-11a (O'Malley, J., concurring in the denial of rehearing). That is incorrect.

a. Respondents first suggest that it would be redundant for the catch-all subcategory "or available to the public" to inform the meaning of the preceding categories, because one of those categories, "in public use," already reflects public activity. See Br. in Opp. 23; see also Pet. App. 9a n.2 (O'Malley, J., concurring in the denial of rehearing).

To the extent that public availability of the claimed invention is inherent in the concept of "public use," however, that does not constitute problematic redundancy; it merely means that the "in public use" subcategory, like the "patented" and "described in a printed publication" categories that precede it, already embodies the concept of public availability, with the catch-all subcategory "or otherwise available to the public" picking up other forms of public availability beyond the enumerated ones. There is nothing odd about the notion that the relevant characteristic in a catch-all provision is intrinsically shared by some of the preceding enumerated categories as well; if anything, that supports petitioner's interpretation, rather than undermining it. See pp. 20-21, *supra*; *Seatrain Lines*, 411 U.S. at 733-734.

In any event, despite the word "public" in the phrase "in public use," the Federal Circuit had construed the pre-AIA version of the public-use bar to reach some uses that did not disclose the claimed inventions to the public. For example, in *New Railhead Manufacturing, L.L.C.* v. *Vermeer Manufacturing Co.*, 298 F.3d 1290 (Fed. Cir. 2002), cert. denied, 537 U.S. 1232 (2003), the court applied the public-use bar where the inventor allowed an acquaintance to test a drill embodying the patented method, even though the method was not otherwise available to the public. See *id.* at 1298. And in *Beachcombers* v. *WildeWood Creative Products, Inc.*, 31 F.3d 1154 (Fed. Cir. 1994), the court applied the public-use bar where the designer of a patented invention displayed it at a party but did not otherwise disclose it to the public. See *id.* at 1159-1160. To the extent there was ambiguity about the scope of the public-use bar as well as the on-sale bar, the AIA eliminated that ambiguity going forward, making clear that a public use, like a sale, must make the claimed invention available to the public. Indeed, as the Federal Circuit acknowledged, the AIA's drafters did cite several pre-AIA public-use cases as examples of the "extreme results" the AIA was designed to avoid. Pet. App. 38a.

b. Respondents further suggest that requiring sales to make the claimed invention available to the public would rob the on-sale bar of any meaning independent from the public-use bar. See Br. in Opp. 21; see also Pet. App. 10a (O'Malley, J., concurring in the denial of rehearing).

That concern is unfounded. To be sure, the on-sale bar and the public-use bar may both apply to the same claimed invention: an invention that is "on sale" can also be "in public use." Indeed, when the Court first articulated the on-sale bar, it treated "sale" and "use" together. See *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1, 23-24 (1829).

But any overlap would exist under either interpretation; it depends on the respective meanings of "sale" and "use," not on whether those actions make the claimed invention available to the public.

At any rate, under petitioner's interpretation, the on-sale and public-use bars would serve independent functions. For example, "[an] offer to sell is enough to bar patentability whether or not the offer is accepted," *A.B. Chance Co.* v. *RTE Corp.*, 854 F.2d 1307, 1311 (Fed. Cir. 1988), while "public use" requires "actual use by someone at some point," *Minnesota Mining & Manufacturing Co.* v. *Chemque, Inc.*, 303 F.3d 1294, 1307 (Fed. Cir. 2002), cert. dismissed, 538 U.S. 972 (2003). As a result, the on-sale bar could apply even where a claimed invention is not yet in public use (if the product is sold but not used, or an offeree declines an offer to sell the product embodying the invention), and the public-use bar could apply even where the invention is not yet on sale (if the product enters the public domain without a sale or offer to sell, such as through an inventor's own use). The critical point is that, under petitioner's interpretation, the on-sale and public-use bars would not be coterminous. See *Dart Industries, Inc.* v. *E.I. du Pont de Nemours & Co.*, 489 F.2d 1359, 1364 & n.8 (7th Cir. 1973) (Stevens, then-J.), cert. denied, 417 U.S. 933 (1974).

c. Respondents also contend that, under petitioner's interpretation, Section 102(a)(1) would conflict with an exception in Section 102(b)(1) for certain disclosures of inventions made before a patent's effective filing date. See Br. in Opp. 25-27; see also Pet. App. 10a-11a (O'Malley, J., concurring in the denial of rehearing). According to respondents, because Congress used the term "disclosure" in Section 102(b)(1)(A) and the phrase "public[] disclos[ure]" in Section 102(b)(1)(B) to describe carve-outs from the definition of prior art in Section 102(a)(1), some

of the covered prior art must not be available to the public. A contrary interpretation, they assert, would render the word "public[]" in Section 102(b)(1)(B) redundant.

That contention misunderstands Section 102(b)(1). That provision excludes certain disclosures from the scope of prior art if they are made within one year before the patent's effective filing date. The exceptions generally apply only to disclosures made by an inventor or someone who obtained the subject matter from an inventor. Section 102(b)(1)(B), however, creates a limited additional exception for disclosures made by third parties; if an inventor "publicly disclose[s]" the "subject matter" of the invention first, then later disclosures (even by third parties) will be exempt if they are made within the one-year period.

By its terms, therefore, Section 102(b)(1)(B) contemplates an *earlier* disclosure of the "subject matter" of the invention. That is a critical distinction. Section 102(b)(1) generally refers to "a disclosure" that otherwise would qualify as prior art "under subsection (a)(1)": *i.e.*, a disclosure that makes the claimed invention available to the public. See pp. 18-24, *supra*. Section 102(b)(1)(A) explicitly excludes certain Section 102(a)(1)-qualifying disclosures. Section 102(b)(1)(B), however, refers to something different: namely, an earlier disclosure of the "subject matter" that is ultimately included in a later Section 102(a)(1)-qualifying disclosure. By including the word "publicly" in Section 102(b)(1)(B), Congress made clear that the earlier disclosure of the subject matter, like the later disclosure, must be public. So understood, the use of "public[]" in Section 102(b)(1)(B) is not redundant, and it is entirely consistent with the plain-text understanding that the triggering action in Section 102(a)(1) must make the claimed invention publicly available.

E. The Plain-Text Interpretation, Not The Federal Circuit's, Better Promotes The Policies Underlying the Patent System

Finally, petitioner's interpretation of Section 102(a)(1) better serves the policies underlying the patent system. It preserves the basic *quid pro quo* of patent law. It prevents uncertainty about the status of prior art that would be harmful to the patent system. And it encourages innovation by affording small inventors an opportunity to develop their inventions.

1. A public-availability requirement is consistent with the fundamental compromise underlying our Nation's patent system. A patent, in effect, is a trade. An inventor gives the public a useful invention and gets a monopoly in exchange. See *Brenner* v. *Manson*, 383 U.S. 519, 534 (1966). That bargain makes no sense if the public already has the invention, because "[t]here would be no quid pro quo—no price for the exclusive right or monopoly conferred upon the inventor." *Pennock*, 27 U.S. at 23. The law, therefore, requires that an invention be both novel and nonobvious. See 35 U.S.C. 102, 103. Together, those requirements prohibit an inventor from obtaining a patent on anything that is "already available to the public" or "readily discern[able] from publicly available material." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989).

The function of prior art is to define what was in the public domain before the invention. And in interpreting the definition of prior art, a court should naturally be guided by that function. In cases involving printed publications, for example, lower courts have held that "[t]he date on which the public actually gained access to the invention * * * is the focus of the inquiry." *In re Bayer*, 568 F.2d 1357, 1361 (C.C.P.A. 1978); see *In re Hall*, 781 F.2d 897, 898-899 (Fed. Cir. 1986). And in interpreting

the on-sale bar itself, this Court has cited the "reluctance to allow an inventor to remove existing knowledge from public use." *Pfaff*, 525 U.S. at 64; see *Bonito Boats*, 489 U.S. at 148-149; *Pennock*, 27 U.S. at 23-24.

Petitioner's interpretation of Section 102(a)(1) is consistent with the function of prior art more generally—and the on-sale bar specifically—in the patent system. A sale to a party obligated to keep an invention confidential, such as petitioner's sale to MGI, does not make the claimed invention available to the public, even if the public knows that a sale has taken place. Permitting petitioner to obtain a patent would therefore not violate the basic *quid pro quo* of patent law, because it would in no way "remove existent knowledge from the public domain." *Graham* v. *John Deere Co.*, 383 U.S. 1, 6 (1966).

2. If it is allowed to stand, the Federal Circuit's interpretation will unleash significant uncertainty throughout the patent system.

For patents to stimulate innovation, their owners must be able reliably to predict their strength. Indeed, "predictability as to the validity of patents" was a core rationale for the establishment of the Federal Circuit in the first place. See Nancy T. Gallini, *The Economics of Patents: Lessons from Recent U.S. Patent Reform*, 16 J. Econ. Persp. 131, 134 & n.4 (2002). The Federal Circuit's decision in this case, however, makes a mockery of that interest. As it stands, the decision will potentially expose patentees to discovery-intensive inquiries into any contacts and communications with third parties regarding the invention—not just in the United States but anywhere in the world, as a result of the AIA's territorial expansion of the definition of prior art. See 157 Cong. Rec. S1371 (statement of Sen. Kyl). That is exactly the kind of impractical burden Congress sought to protect against when

it set out to "provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries." Pub. L. No. 112-29, § 3(o), 125 Stat. 293.

3. By contrast, if it is adopted by this Court, petitioner's interpretation will foster the collaborative work that leads to innovation, especially by small inventors. A patent functions as an "incentive to inventors to risk the often enormous costs in terms of time, research, and development." *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 480-481 (1974). This is true across all industries, but it is particularly true in the pharmaceutical industry, where the discovery of new drugs is expensive and unpredictable. See generally Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20 (2016) (estimating the total pre-approval cost of developing a new drug at $2.6 billion). Even large pharmaceutical companies enter into development partnerships to share risk and defray cost. Small companies such as petitioner often have no choice: they must enter into such partnerships because they do not have the resources to develop and bring drugs to market on their own.

The Federal Circuit's interpretation puts the small companies that have to seek such partnerships at a marked disadvantage. Under the Federal Circuit's rule, any public reference to the existence of development arrangements could qualify as patent-defeating prior art. And where, as here, the development partner is itself a relatively small company, the securities laws may compel disclosure of the material fact that such an agreement exists. See Pet. App. 38a.

At a minimum, therefore, the Federal Circuit's decision has the "potential to chill deals between small bio/pharma companies and potential commercialization

partners." Andrew D. Cohen & Irena Royzman, *The Federal Circuit's First Application of the AIA's On-Sale Bar: Implications for Bio/Pharma*, Biologics Blog (May 16, 2017) <tinyurl.com/biologicsblog>. And at worst, it will prevent small companies such as petitioner from bringing new drugs to market altogether, with obvious harm to the consumers who depend on those products.

The Federal Circuit's interpretation of Section 102(a)(1) is thus not only inconsistent with the statutory text and legislative history; it is also bad policy. Rarely in a statutory-interpretation case do all of the relevant considerations point so clearly in the same direction. The Federal Circuit's decision is indefensible. Its judgment should accordingly be reversed.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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AUGUST 2018

No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., ET AL.,

Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

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October 9, 2018

QUESTIONS PRESENTED

For nearly two centuries, the Patent Act has prohibited inventors from obtaining a patent if the invention is "on sale" before the inventor applies for a patent, subject to a grace period (currently one year). 35 U.S.C. § 102(a). Since 2011, the Patent Act has also prohibited inventors from obtaining a patent if the invention is "otherwise available to the public" outside the grace period. *Id.*

Petitioner's invention was ready for patenting, but petitioner did not apply for a patent until more than a year after selling the invention to a distributor for $11 million.

The questions presented are:

1. Whether the 2011 amendment changed the meaning of "on sale" so that commercial sales no longer start the grace period unless they *also* make the invention "available to the public."

2. If the 2011 amendment changed the meaning of "on sale," whether petitioner nonetheless placed its invention "on sale" when it sold the invention for $11 million and disclosed every element of the invention to the buyer.

RULE 29.6 STATEMENT

The parent companies of Teva Pharmaceuticals USA, Inc. are: Orvet UK Unlimited, Teva Pharmaceutical Holdings Coöperatieve U.A., Ivax LLC (f/k/a IVAX Corporation), Teva Pharmaceuticals Europe, B.V., and Teva Pharmaceutical Industries Ltd. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Pharmaceuticals USA, Inc.

Teva Pharmaceutical Industries Ltd. has no parent company, and no publicly traded company owns 10% or more of the stock of Teva Pharmaceutical Industries Ltd.

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INTRODUCTION

This case is about the meaning of "on sale"—a term Helsinn never bothers to define. That term has a simple meaning that this Court has applied since the 1800s: an item is "on sale" if it is sold or offered for sale, even to a single buyer. Therefore, when Helsinn sold its pharmaceutical product to a commercial distributor for $11 million, the product was "on sale," and Helsinn had one year to seek a patent. Helsinn's attempt to avoid that straightforward conclusion depends on an unnatural meaning of "on sale" that focuses not on commercialization, but on disclosure.

Helsinn sought to do what this Court has held for nearly two centuries is impermissible: "exploit [a] discovery competitively after it is ready for patenting," while delaying applying for a patent. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68 (1998) (citation omitted). Patents confer a monopoly "'for limited times,'" and allowing inventors to place their inventions on sale immediately but to defer seeking a patent until much later—when they are faced with "the danger of competition"—would extend the period of monopoly, reward delay in publicizing discoveries, and "materially retard the progress of science." *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 16, 19 (1829) (Story, J.) (quoting U.S. Const. Art. I, § 8, cl. 8). That is why Congress enacted the on-sale bar that now appears in 35 U.S.C. § 102(a).

This Court has always read "on sale" as a term of art that encompasses even a single sale or offer to sell, whether or not the sale or offer publicly discloses the invention's details. The on-sale bar is triggered by commercial exploitation—*not* public dissemination of every detail of the invention. Offers for

sale, for example, do not generally teach the public everything about the invention, but this Court has squarely held that an offer places the invention "on sale." And while other bars in Section 102(a) incorporate concepts of broader public availability—*e.g.*, "public use" or disclosure in a "printed publication"—this Court has always read "on sale" to encompass even "a single instance of sale." *Consol. Fruit-Jar Co. v. Wright*, 94 U.S. 92, 94 (1877). The on-sale bar asks not whether the *public* derives knowledge, but whether the *inventor* "derive[s] any benefit from the sale" of an invention that is ready for patenting. *Id.* (citation omitted).

According to Helsinn, the 2011 amendment fundamentally changed the scope and function of the on-sale bar—not directly, but with a bank shot. Congress did not change the phrase "on sale" at all; it added a *new* category of invalidating prior art, consisting of disclosures that make an invention "otherwise available to the public." Helsinn now agrees that the new phrase "to the public" does not modify "on sale" as a grammatical matter; instead, Helsinn contends that this new language "informs" the meaning of "on sale" in some less tangible way. But Congress does not generally alter the well-established meaning of a statutory term of art by amending *other* statutory language, and it did not do so here.

Indeed, Helsinn's reading would not only *change* the term of art's meaning, but *drain* it. A sale would be left as nothing more than an example of a disclosure that makes the invention "available to the public." That reading is not necessary to give the catchall phrase meaning, as Helsinn insists. The term "otherwise" merely acknowledges *some* overlap

between that new category and the pre-existing ones in the statute (which include "public use" and disclosure in a "printed publication"). It does not signal that the settled meaning of "on sale" must be compressed to achieve *complete* overlap with the new category—which would leave the on-sale bar with nothing independent to do. Moreover, if all disclosures under Section 102(a) now are *necessarily* "public," it is impossible to make sense of the following subsection of the statute, which expressly distinguishes between "disclosures" and "public disclosures."

In adopting the 2011 amendment, Congress did not seek to neutralize the on-sale bar. To the contrary, Congress *retained* the on-sale bar, and proposals to do precisely what Helsinn wants were *rejected* based on "strenuous concerns" from "a wide range of stakeholders" about "delet[ing] specific categories of prior art with well established meanings in case law." House Comm. on the Judiciary, *Markup of H.R. 1249, The America Invents Act* 101 (Apr. 14, 2011) ("*Markup*") (statement of Rep. Lofgren).[1] The legislative history Helsinn now cites comes from Members of Congress who wanted to eliminate the on-sale bar; criticized the draft legislation for retaining it; and after failing to kill it, resorted to floor statements opining that the on-sale bar does not cover the very sales *they had criticized it for covering*. This Court should not do what Congress itself would not.

Even if Helsinn were right that a sale or offer must make the invention "available to the public," Helsinn does not even attempt to explain why its multimil-

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[1] Available at https://tinyurl.com/MarkupTrans.

lion-dollar sale to a distributor did not do just that. Helsinn sold the entire invention to a member of the interested public—exactly the type of customer one would expect to buy a pharmaceutical from its manufacturer. The government's proposed standard, which focuses on whether the "ultimate customer" could acquire the invention, has no basis in the statute's text and would be impossible to administer.

This Court should affirm.

STATUTORY PROVISIONS INVOLVED

1. Section 3(b)(1) of the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284, 285-286 (2011), amended 35 U.S.C. § 102 to provide, in relevant part:

> (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
>
> > (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention * * * .
> >
> > * * * *
>
> (b) EXCEPTIONS.—
>
> > (1)DISCLOSURES MADE 1 YEAR OR LESS BEFORE THE EFFECTIVE FILING DATE OF THE CLAIMED INVENTION.—A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if—

> (A) the disclosure was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
>
> (B) the subject matter disclosed had, before such disclosure, been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

2. 35 U.S.C. § 102 (2006) provided, in relevant part:

> A person shall be entitled to a patent unless—
>
> * * *
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

STATEMENT

A. Well before the 2011 amendment, 200 years of precedent confirmed that an invention can be "on sale" without disclosing every element of the invention to the public.

An inventor must apply for a patent promptly after placing a completed invention "on sale." 35 U.S.C.

§ 102(a). For nearly two centuries, this Court has focused the on-sale analysis on sales and offers that commercially exploit the invention, regardless of whether they disclose every element of the invention to the public.

The Court first identified commercial exploitation as invalidating in *Pennock*. The inventor had used a new process to make fire hose and sold it to several companies before seeking a patent on the process. 27 U.S. at 3. The Court held that an inventor can no longer get a patent "if he suffers the thing invented to go into public use, or to be publicly sold for use, before he makes application for a patent." *Id.* at 23-24. The patent therefore was invalid—even though there was no indication that selling the hose had publicly disclosed the claimed manufacturing process.

Pennock established a principle that still animates the on-sale bar: inventors may not profit commercially from their inventions, but delay seeking patents (beyond a limited grace period, currently one year). As *Pennock* put it, allowing an inventor to "retain the monopoly, and make and sell his invention publicly; and thus gather the whole profits of it, relying upon his superior skill and knowledge of the structure," and then to "take out a patent, and thus exclude the public from any further use," only when "the danger of competition should force him to procure the exclusive right," would "materially retard the progress of science and the useful arts; and give a premium to those who should be least prompt to communicate their discoveries." *Id.* at 19.

Soon after *Pennock*, Congress expressly prohibited patenting an invention already "on sale." Patent Act

of 1836, ch. 357, § 6, 5 Stat. 117. Ever since, courts applying the bar have followed *Pennock* in holding that "an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law." *Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 137 (1878). Similarly, "the inventor who designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public, ... does not promote, and, if aided in his design, would impede, the progress of science and the useful arts." *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1859).

Judge Learned Hand likewise cited *Pennock* in a landmark decision holding that "secret" sales invalidated a patent. He concluded that "it is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2d Cir. 1946). Because the inventor sold his invention outside the grace period, the on-sale bar applied "regardless of how little the public may have learned about the invention" from the "secret" sales. *Id.* at 518, 520. As in *Pennock*, the key principle was preventing commercial exploitation before the patent application. This Court has twice unanimously endorsed *Metallizing*'s holding that an inventor "shall not exploit his discovery competitively after it is ready for patenting." *Pfaff*, 525 U.S. at 68; *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 149 (1989).

This Court most recently considered the scope of the on-sale bar in *Pfaff*. More than a year before applying for a patent, the inventor there made an agreement to sell to a single corporate buyer, based on "detailed engineering drawings" and "a sketch of his concept." 525 U.S. at 58. Although this agreement did not make the invention (as later patented) available to the general public, the sale triggered the on-sale bar. *Id.* at 68-69.

As the Court explained, the "patent system represents a carefully crafted balance ... between the interest in motivating innovation and enlightenment by rewarding invention with patent protection on the one hand, and the interest in avoiding monopolies that unnecessarily stifle competition on the other." *Id.* at 63. Citing *Pennock* and *Metallizing*, the Court held that the on-sale bar "confin[es] the duration of the monopoly to the statutory term." *Id.* at 64. The Court thus applied a two-part test for finding an invention "on sale" and starting the one-year clock: The invention must be "the subject of a commercial offer for sale," as opposed to an experimental one, and must have been "ready for patenting." *Id.* at 67. Whether the offer fully disclosed the invention to the buyer was irrelevant.

Consistent with these precedents, the Federal Circuit has repeatedly applied the on-sale bar to non-public sales.[2] As that court has explained, "the pri-

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[2] *E.g.*, *Merck & Cie v. Watson Labs., Inc.*, 822 F.3d 1347, 1351 (Fed. Cir. 2016) (responding to a single customer's request to purchase product by returning price, delivery, and payment terms triggered the on-sale bar); *Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328 (Fed. Cir. 2001) (offer to sell a service

mary policy underlying an 'on-sale' case is that of prohibiting the commercial exploitation of the design beyond the statutorily prescribed time period." *Cont'l Plastic Containers v. Owens Brockway Plastic Prods., Inc.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998). Indeed, the en banc Federal Circuit recently called it "'well established ... that a single sale or offer to sell is enough to bar patentability' even if kept secret from the trade." *Meds. Co. v. Hospira, Inc.*, 827 F.3d 1363, 1376 (Fed. Cir. 2016) (en banc) (quoting *In re Caveney*, 761 F.2d 672, 676 (Fed. Cir. 1985)).

B. Members of Congress repeatedly tried and failed to amend the AIA to abandon the on-sale bar in favor of a general "public availability" inquiry.

The AIA retained the on-sale bar, despite attempts by some Members of Congress to eliminate it. While Congress added a new catchall category of invalidating prior art—art that makes the claimed invention "otherwise available to the public"—the statute continues to provide that a patent is invalid if the invention was "on sale" more than one year before the patent application. 35 U.S.C. § 102(a).[3] Throughout the multi-year process of drafting the AIA, proponents and opponents of the on-sale bar agreed that, *if* the bar remained (as it ultimately did), it would keep its longstanding meaning.

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that would have necessitated use of a certain process triggered the on-sale bar as to that process).

[3] The one-year grace period was moved into a separate subsection, Section 102(b). The AIA also amended that subsection to distinguish for certain purposes between "disclos[ures]" and "*public* disclos[ures]" by the inventor during the grace period. *See* pp. 37-39, *infra*.

The first two predecessor bills were introduced in 2005 and 2006 by Representative Smith and Senator Hatch. These bills would have removed the on-sale bar altogether, denying a patent only if "the claimed invention was patented, described in a printed publication, or otherwise publicly known." H.R. 2795, 109th Cong. § 3(b)(1) (2005); S. 3818, 109th Cong. § 3(b)(1) (2006). The "otherwise publicly known" language from this bill could not have been crafted to "inform" the meaning of "on sale," as the bill would have *deleted* that term.

The next year, the House considered a new bill that retained the on-sale bar, making a patent unavailable if the invention was "patented, described in a printed publication, or in public use or on sale" outside the grace period. H.R. 1908, 110th Cong. § 3(b)(1) (2007); *see also* S. 1145, 110th Cong., § 3(b)(1) (2007). The committee report stated that the bill used the phrase "on sale" because it "ha[d] been interpreted by the courts." H.R. Rep. No. 110-314, at 57 (2007).

The report also explained that the on-sale bar was intended to serve "very specific policy goals," including "encouraging inventors to file early for patent protection" and "preventing inventors from extending their monopoly in the invention." *Id.* The report confirmed that these incentives were still needed even if (as the bill also proposed) the United States shifted to "a first-to-file system." *Id.*

Subsequent proposals differed over whether to retain the "public use" and "on sale" bars (as in the House's 2007 bill) or replace them with a general "available to the public" standard (as in the House and Senate's 2005 and 2006 bills). In 2008, Senator

Leahy introduced a bill with language identical to the AIA's. S. 1145, 110th Cong. § 2(b)(1) (2008) ("patented, described in a printed publication, or in public use, on sale, or otherwise available to the public").

By contrast, Senator Kyl introduced a bill that deleted the "public use" and "on sale" bars in favor of "a uniform test of whether art has been made available to the public." S. 3600, 110th Cong. § 2(b)(1) (2008) ("patented, described in a printed publication, or otherwise made available to the public"). Senator Kyl said that his bill, *unlike Senator Leahy's*, would "eliminat[e] confidential sales and other secret activities as grounds for invalidity and impos[e] a general standard of public availability." 154 Cong. Rec. 22,631 (2008).

Senators Leahy and Kyl introduced similar bills the next year. S. 515, 111th Cong. § 2(b)(1) (2009); S. 610, 111th Cong. § 2(b)(1) (2009). Once again, Senator Kyl stated that he read Senator Leahy's bill to preserve the existing meaning of the on-sale bar, criticizing that bill for retaining "patent-forfeiture provisions that apply only to non-public prior art." S. Rep. No. 111-18, at 60 (2009) (minority views).

In reporting the bill that became the AIA, the House Judiciary Committee rebuffed a final attempt to replace the on-sale bar with a general "available to the public" standard. As introduced, the House bill included the language now found in the AIA. H.R. 1249, 112 Cong. § 2(b)(1) (2011). Representative Smith proposed amending Section 102(a) to "strike 'or in public use, on sale, or otherwise available to the public' and insert 'or otherwise disclosed to the public.'" Amendment to H.R. 1249 Offered by Mr.

Smith of Texas, at 2 (Apr. 12, 2011).[4] The effort quickly failed: Representative Lofgren proposed a successful amendment restoring the text of Section 102 as introduced (and as ultimately enacted). *Markup* 101.[5] As she explained: "I have now heard strenuous concerns about the broader change from a wide range of stakeholders. In particular, they are concerned about the deletion of specific categories of prior art with well established meanings in case law and replacing those terms with a more ambiguous term otherwise disclosed to the public." *Id.* Her amendment thus preserved the on-sale bar, with its "well established meaning[]." *Id.*

C. Helsinn earns millions of dollars selling the invention to its distributor, but delays seeking a patent.

1. This case involves the use of intravenous formulations of palonosetron to treat chemotherapy-induced nausea and vomiting ("CINV"). A prior-art patent disclosed the palonosetron compound and described it as useful for preventing and treating "emesis"—*i.e.*, nausea and vomiting, including CINV. The prior art disclosed that an ordinarily skilled artisan "will be able, without undue experimentation, to ascertain" the effective doses for particular diseases. Pet. App. 68a-69a. In turn, Phase II clinical trials demonstrated that the 0.25 mg (3 μg/kg) dosage was "effective in suppressing chemotherapy-induced emesis for 24 hours." J.A. 33.

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[4] Available at https://tinyurl.com/SmithAmdt.

[5] Available at https://tinyurl.com/LofgrenAmdt.

In 1998, Helsinn purchased a license to develop palonosetron. Pet. App. 78a. Helsinn's plan, according to internal minutes, was to "test effective doses seen in Phase 2," including "0.25 mg." J.A. 38. Over several years, Helsinn repeatedly reiterated that Phase II trial results had confirmed palonosetron's efficacy in treating CINV at dosages including 0.25 mg, telling FDA that "[0.25 mg] is the minimal *effective* dose." J.A. 48; *see also* J.A. 50.

Thus, when Helsinn acquired its license to palonosetron, the 0.25 mg dose had already been "shown ... to work for its intended purpose." Pet. App. 44a. Nonetheless, Helsinn did not apply for a patent.

2. Meanwhile, Helsinn sought to profit commercially from the unpatented invention. In April 2001, Helsinn entered into a Supply and Purchase Agreement and a License Agreement with MGI Pharma, a distributor. J.A. 52-250. MGI agreed to buy the 0.25 mg dose and resell it to pharmacies. MGI paid Helsinn $11 million upon signing, and promised future payments, for Helsinn's commitment to supply MGI with whatever product it might need upon FDA approval. J.A. 80-87. Both courts below concluded (and Helsinn no longer disputes, *see* Pet. i) that Helsinn had made a "sale" of the invention under the Uniform Commercial Code ("UCC"), even though it was partially contingent on FDA approval. Pet. App. 33a, 164a.

Virtually every detail of the sale was publicized in a joint Helsinn/MGI press release and SEC filings. Both included a redacted version of the parties' agreements and described most of the financial terms. J.A. 253, 258. Copies of the agreements, including "[d]etailed information about palonosetron"

and its "chemical structure," were attached to SEC Form 8-K. Pet. App. 38a; J.A. 333-370. The sale thus publicized every aspect of the invention, and "all the pertinent details of the transaction," "other than the price and dosage." Pet. App. 39a.

3. Nearly two years later, on January 20, 2003, Helsinn finally filed a provisional patent application. Pet. App. 61a. The critical date for the on-sale bar is thus January 20, 2002—one year earlier. *Id.* Helsinn ultimately obtained four patents. *Id.* at 61a-63a. Because only U.S. Patent No. 8,598,219 ("the '219 patent") is governed by the AIA, however, only that patent remains at issue. *Id.* at 61a. It describes an intravenous dose of 0.25 mg of palonosetron, in a 5 mL volume, for treating CINV. J.A. 484-485.

4. In 2011, Teva filed an Abbreviated New Drug Application ("ANDA") to produce a generic version of palonosetron at the 0.25 mg dose for treating CINV. Pet. App.144a-145a. Teva's ANDA included a "Paragraph IV" certification to the '219 patent, which asserts that the patent is invalid, unenforceable, or would not be infringed by the proposed generic product. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

D. The district court finds a "sale" but upholds the patent.

Filing a Paragraph IV certification is itself an act of infringement, 35 U.S.C. § 271(e)(2)(A), so Helsinn sued Teva, alleging that the proposed generic product would infringe Helsinn's four patents. Pet. App. 53a-54a. Teva answered that the patents were invalid because of Helsinn's 2001 sale to MGI, arguing both that the on-sale bar still applied to private sales and that the MGI sale was to the public in any event.

After a bench trial, the district court held that the patents were all valid and infringed. As noted above, it found that the Helsinn/MGI Supply and Purchase Agreement qualified as a "commercial sale" for purposes of the pre-AIA on-sale bar. *Id.* at 164a. But the court held that "the post-AIA on-sale bar" requires not just a "sale" (or offer), but one that "make[s] the claimed invention available to the public." *Id.* at 180a. The court acknowledged that Helsinn and MGI had publicized their agreement, but deemed this insufficient because they did not disclose every limitation later claimed in the patent. *Id.*

E. The Federal Circuit holds that Helsinn's multimillion-dollar sale of the invention to its distributor started the clock to seek a patent.

1. The Federal Circuit reversed. It first affirmed that, under the UCC, Helsinn sold "the claimed invention—the 0.25 mg dose—before the critical date," noting that the parties' agreement "described the palonosetron formulation in detail" and that the 0.25 mg dose "embod[ies] the asserted claims." Pet. App. 33a.

Turning to whether the AIA "changed the meaning of the on-sale bar," the court declined to read the addition of "otherwise available to the public" to work "a foundational change in the theory of the statutory on-sale bar" dating back to *Pennock*. *Id.* at 39a. As the court explained, the bar has been applied in numerous situations, including: "when there is no delivery" of the product because an offer is rejected; "when delivery is set after the critical date" (*i.e.*, one year before the patent application); "or, even when,

upon delivery, members of the public could not ascertain the claimed invention." *Id.* at 42a. "If," as Helsinn argued, "Congress intended to work ... a sweeping change" to this broad scope, it would have used "clear language," rather than leaving the on-sale bar itself unchanged while adding a new, separate category of invalidating prior art. *Id.* at 43a.

The court also rejected Helsinn's legislative-history arguments, based primarily on "floor statements" of "individual members of Congress." *Id.* at 36a. Such statements, the court observed, are "typically not reliable." *Id.* Moreover, the statements at most suggested that Congress may have meant to "overrule" cases where the existence of the sale itself was confidential. *Id.* at 38a. Here, "the existence of the sale—*i.e.*, the Supply and Purchase Agreement between Helsinn and MGI—was publicly announced in MGI's 8-K filing," resulting in public disclosure of "all the pertinent details of the transaction other than the price and dosage levels." *Id.* Thus, even if Congress had incorporated a "public disclosure" requirement into the on-sale bar, Helsinn's sale would satisfy it.

Finally, the court held that Helsinn's invention had been "overwhelming[ly]" ready for patenting since the mid-1990s, and certainly as of January 30, 2002, the critical date. *Id.* at 47a, 43a-52a. Because both prongs of *Pfaff* were therefore satisfied, the court concluded that all four patents-in-suit were "invalid under the on-sale bar." *Id.* at 52a.

2. The Federal Circuit denied rehearing *en banc*. Judge O'Malley concurred. Citing "[the] cardinal rule" that, "when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the

body of learning from which it was taken," she stressed that "Congress chose not to modify the term 'on sale'" and thus "intended for that term to take on the meaning that courts had attributed to it for well over a century." *Id.* at 9a-10 (citation omitted).

Judge O'Malley also explained that "Helsinn's only argument directed to the text"—"that the new phrase 'or otherwise available to the public'" changes the settled meaning of "'on sale'"—had "several problems." *Id.* at 8a. For example, Helsinn had argued that "to the public" actually modifies "on sale" in addition to "otherwise available." Judge O'Malley explained that series modifiers must "appl[y] as much to the first and other words as to the last"; but "to the public" is "not equally applicable to all preceding phrases because each phrase ... recites a disclosure that is necessarily public. Helsinn's reading ... would therefore create redundancies." *Id.* at 9a & n.2. Further, Section 102(b)(1)—which creates a one-year grace period for Section 102(a) disclosures—distinguishes between "disclosures" and "public disclosures." *Id.* at 11a. But "[i]f all prior art events—i.e., all 'disclosures'—recited in §102(a) were already public disclosures, the word "publicly ... would be redundant." *Id.*

Because Helsinn's reading conflicted "with so many principles of statutory interpretation," Judge O'Malley read the addition of "otherwise available" not as limiting what was already in the statute, but as broadening it with "a catchall provision that encompasses ... disclos[ures] to the public that are not otherwise accounted for in § 102(a)." *Id.* at 9a. She saw no basis to disturb the on-sale bar's longstanding interpretation, especially given its "overriding

concern" with preventing "an inventor" from "commercially exploit[ing] his invention beyond the statutory term." *Id.* at 11a, 13a.

SUMMARY OF ARGUMENT

I. Making an invention available for purchase by selling it or offering it for sale places that invention "on sale." That is what "on sale" has always meant and how this Court has consistently read it. The AIA did not give that phrase a new and unnatural meaning that would reverse centuries of precedent.

A. Placing something "on sale" means making it "available for purchase." *Merriam-Webster's Collegiate Dictionary* 1097 (11th ed. 2003) ("*Webster's Collegiate*"). A good or service that *has been* sold or offered for sale has thus necessarily been placed "on sale." Nothing about the ordinary meaning of "on sale" requires that a sale or offer be *public*, let alone that it publicly disclose any particular details about what is being sold.

Consistent with the ordinary meaning of "on sale," this Court has long held—from *Pennock* through *Pfaff*—that a sale or offer for sale to even *one* buyer, at any level of the distribution chain, triggers the on-sale bar regardless of what is disclosed to the public. What matters is whether the inventor derives commercial benefit, not whether the public derives knowledge.

B. Had Congress intended to change the ordinary and settled meaning of "on sale," it would have done so directly and expressly. When Congress intends to change the meaning of a term of art or language that this Court has construed, it does so clearly. The phrase "on sale" has just such a settled meaning.

The AIA did not amend "on sale" *at all*, and certainly did not clearly signal a radical change to its meaning.

C. Congress did not *indirectly* change the meaning of "on sale" by adding a new category of invalidating prior art—disclosures making the invention "otherwise available to the public." That new, catch-all category was added to ensure that the statute captures all public disclosures of the invention; oral presentations, for example, were not previously covered. That is not only the catch-all's "most obvious purpose," U.S. Br. 18, but its *only* purpose.

Helsinn claims (at 39) that if the catch-all did not also "inform"—*i.e.*, change—the meaning of "on sale," then "otherwise" would be superfluous. Helsinn is wrong. The word "otherwise" acknowledges the significant overlap between the catchall and the pre-existing categories. But "otherwise" does not signal that *everything* previously covered would now fall into the catchall.

Helsinn's reliance (at 20) on the *noscitur a sociis* canon is misplaced. Whatever value that canon may have when an ambiguous term has multiple potential meanings, it cannot "create ambiguity where the statute's text and structure suggest none." *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 227 (2008). Helsinn improperly invokes *noscitur a sociis* to force an unnatural meaning onto an unambiguous term—based on language added to the statute long after the term's meaning was settled. Further, the canon does not apply where, as here, terms are not susceptible to a common interpretation without robbing them of their "independent and ordinary significance." *Graham Cty. Soil & Water Conservation Dist. v. United*

States ex rel. Wilson, 559 U.S. 280, 288 (2010) (citation omitted).

D. The distinction between "disclosure[s]" and "public[] disclos[ures]" in Section 102(b)(1)(B) is further evidence that Helsinn's interpretation is incorrect. If Helsinn were right that all disclosures under Section 102(a) must be public, then the word "publicly" in Section 102(b) would do no work.

E. The AIA's drafting history powerfully confirms that the amendment did not change the meaning of "on sale." The new prior-art category was added to the statute in bills that *did not include* the on-sale bar, and hence could not have been written to modify it. That history also refutes the notion that "otherwise" serves no function except to "inform" the on-sale bar. Further, the extended disagreement over whether to *replace* the on-sale bar with a public-availability standard belies Helsinn's argument that the two formulations mean the same thing. And contemporaneous statements confirm that retaining the bar meant retaining its existing meaning.

The floor statement by Senator Kyl on which Helsinn heavily relies (at 27-28) shows why floor statements "rank among the least illuminating forms of legislative history." *NLRB v. SW General, Inc.*, 137 S. Ct. 929, 943 (2017). Senator Kyl repeatedly urged his colleagues *not* to adopt the same wording that the AIA ultimately used, because that wording would *preserve* the existing meaning of the on-sale bar. When that effort failed, he began arguing that the AIA's language actually *changed* the bar's meaning—attempting to accomplish through the *Congressional Record* what he failed to do in the AIA itself.

F. Helsinn's position would leave the on-sale bar incapable of serving the role for which it was created: preventing monopolies from being extended by a lengthy period of commercialization before the patent term. Inventors could immunize an unlimited number of sales from the on-sale bar simply by having the purchasers sign non-disclosure agreements. And Helsinn's approach would effectively overturn this Court's holding that *offers* for sale place the invention "on sale," as an *offer* generally need not disclose the invention's details.

These concerns remain real in a first-to-file system. Many inventors—particularly inventors of manufacturing processes—will remain motivated by the profits from extending patent monopolies to conceal inventions before seeking a patent. And the House Judiciary Committee recognized that "preventing inventors from extending their monopoly" remains relevant "in a first-to-file system" because inventors will "mak[e] use of their inventions as trade secrets and then some time later fil[e] a patent application." H.R. Rep. No. 110-314, at 57.

G. Helsinn's arguments invoking other AIA provisions (at 33-35) are also unavailing. Because the AIA consciously retained the term "on sale," which does not appear in other countries' patent laws, it is unnecessary—indeed, impossible—to read the term as if the United States had fully adopted foreign conceptions of prior art. The fact that the AIA made international sales invalidating simply expands the bar's geographic scope; it does not change the meaning of "on sale." And applying the on-sale bar's longstanding interpretation would not complicate the post-grant-review process.

II. Even if the on-sale bar were limited to sales or offers that make inventions "available to the public," the Court should still affirm. The only way to harmonize the on-sale bar with a public-availability requirement is to hold that a sale or offer triggers the bar if it discloses the invention to a member of the public one would expect to purchase it. The government's test—that the invention must be available to "ultimate customers"—has no basis in *either* the phrase "on sale" or "available to the public." On the government's view, an invention could be *repeatedly* sold without having been placed "on sale." And while offering to sell to *one* "ultimate customer" would make the invention "available to the public," selling to *every wholesaler and retailer in the world* would not. That interpretation is neither correct nor coherent.

Helsinn's $11 million sale to its distributor made the invention available to the public. There is no dispute that Helsinn's sale disclosed every element of its invention to MGI. Nor is there any doubt that MGI, a pharmaceutical distributor, is *precisely* the kind of member of the public one would expect to purchase the invention. Selling the invention for millions of dollars and disclosing every element to the purchaser placed the invention "on sale."

ARGUMENT

I. The America Invents Act did not narrow the well-established meaning of the on-sale bar by adding a new category of invalidating prior art.

Offering an item for sale—whether to one private buyer or the whole world—places it "on sale." That

is how this Court has long read the on-sale bar, and Congress has not changed the term's meaning. The addition of the "otherwise available" phrase at the end did not reverberate back through Section 102(a) to upset the settled meaning of other terms that Congress left in place.

A. An invention is "on sale" when offered for sale.

Helsinn's interpretation of "on sale" cannot be squared with its ordinary meaning—a meaning confirmed by this Court's longstanding interpretation. Helsinn has conceded that "on sale" is a term of art under that precedent, but says the AIA changed its meaning, such that inventors may offer or sell their inventions repeatedly without *ever* putting them "on sale." In reality, however, *any* sale or offer places the invention "on sale," regardless of whether it discloses the details of the invention to the public.

1. The phrase "on sale" encompasses *any* sale or offer for sale. A "sale" means simply a "transfer of ownership of and title to property ... for a price." *Webster's Collegiate* 1097; *accord* N. Webster, *An American Dictionary of the English Language* 719 (13th ed. 1834) ("the exchange of a commodity for money of equivalent value"); *Concise Oxford English Dictionary* 1268 (12th ed. 2011) (defining "sale" as "the exchange of a commodity for money"). Sales are about *ownership*, not *disclosure*, and nothing in standard dictionary definitions of "sale" turns on whether the purchaser agreed to keep confidential the sale or the item sold.

To put a good or service "*on* sale" is thus simply to make the good or service "*available* for purchase"—

i.e., available for money. *Webster's Collegiate* 1097 (emphasis added); *accord Concise Oxford English Dictionary* 1269 ("offered for purchase"); J. Worcester, *Dictionary of the English Language* 1266 (1860) ("to be sold"). An item is no less "on sale" if it is "the subject of a commercial offer for sale" that is not accepted. *Pfaff*, 525 U.S. at 67. Moreover, *nothing* in the term's ordinary meaning suggests that whether an item is "on sale" requires asking whether a sale or offer occurs privately, or happens to publicly disclose the object of the sale. Consumer goods are no more "on sale" than, say, private-placement securities—which by definition are offered for sale privately.

Helsinn does not engage *at all* with the meaning of "on sale." As noted (p. 13, *supra*), Helsinn does not even dispute that there was a "sale" here. The government insists (at 15) that the term "inherently suggests a sale or offer to sell to the public." But its only support is a dictionary that defines "on sale" as "[a]vailable *to customers*." U.S. Br. 15. As the same dictionary confirms, a "customer" is simply "one that buys goods or services," not necessarily the end user or the public at large. *American Heritage Dictionary of the English Language* 449 (5th ed. 2011). And while the government cites several popular articles that use "on sale" to describe consumer products available to the general public, that does not narrow the term's meaning. The popular press uses "on sale" regardless of whether the "sale" will be to the general public. *E.g.*, *Technology Brief*, Wall St. J., Sept. 3, 2003, at A12 ("[T]he Gyricon unit's signs are expected to go *on sale to retailers* next year.") (emphasis added). A product is "on sale" if a buyer can buy it.

2. The ordinary meaning of "on sale" perfectly tracks this Court's longstanding interpretation of the on-sale bar. As Helsinn conceded below, by the time of the AIA, "on sale" had become a "term[] of art." C.A. Br. 43. Beginning in *Pennock* and continuing through *Pfaff*, the Court repeatedly applied the bar to offers and sales without asking whether the offers or sales were sufficiently broad or revealing to disclose the nature of the invention to the general public. For instance, the invalidating offer in *Pfaff* was made to a single corporation, Texas Instruments. 525 U.S. at 58. *See also, e.g., Smith & Griggs Mfg. Co. v. Sprague*, 123 U.S. 249, 257 (1887) ("A single sale to another"); *Hall v. Macneale*, 107 U.S. 90, 97 (1883) (sale of two safes containing patented bolts, which could not be viewed without "destruction of the safes"); pp. 5-8, *supra*.

The rationale of these cases—that the on-sale bar precludes attempts to extend the patent term and thus to gain a longer monopoly—confirms that triggering the bar does not turn on how much the sale or offer discloses. What matters is not whether the public derives knowledge, but whether the *inventor* "derive[s] any benefit from the sale." *Consol. Fruit-Jar*, 94 U.S. at 94 (citation omitted).

Indeed, this principle applies with the *most* force to inventions that are *not* publicly disclosed through an offer or a sale—when inventors have the least reason to fear competition. As in *Pennock*, for example, the inventor of a new manufacturing *process* can often sell the end product without disclosing the process itself. *See, e.g., Metallizing*, 153 F.2d at 519.

Similarly, this Court's unambiguous holding that *offers* for sale trigger the bar, *Pfaff*, 525 U.S. at 67,

did not ask whether the offer communicated the entire invention, and such a rule would make no sense. A seller marketing an unpatented invention would rarely (if ever) disclose every detail of the invention *in the offer*. Offers trigger the bar not because they teach the public anything, but because the inventor is commercializing an invention ready for patenting.

As this Court has held (quoting Judge Hand), an inventor "shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." *Pfaff*, 525 U.S. at 68 (quoting *Metallizing*, 153 F.2d at 520). Inventors may not have it both ways—exploiting their inventions secretly while fearing no competition, and then getting patents (and extending their monopolies) once competition is threatened.

B. Congress would act expressly if it sought to change the term's settled meaning.

Rather than engage with the term "on sale" or the case law interpreting it, Helsinn and the government say Congress changed the term's meaning without actually touching it. By their lights, Congress's *expansion* of the categories of prior art that invalidate patents—to include inventions "otherwise available to the public"—*shrunk* the phrase "on sale" to reach only offers and sales of an invention that *publicly disclose every element of the invention*. But assertions that Congress changed the Court's settled interpretation of statutory language must clear a high bar, especially when based on changes to *nearby* statutory language rather than the operative text.

Helsinn cannot surmount that bar here. The AIA retained the term "on sale" unchanged, without lim-

iting it to public sales, leaving it in a list of bars that *do* repeatedly include the word "public." Congress's word choice powerfully confirms that it did not "work a foundational change" in the on-sale bar. Pet. App. 39a. The change Congress did make—adding "otherwise available to the public"—fills a gap by creating a catchall category of invalidating prior art; it does not modify the scope of the preexisting categories.

1. "It is a cardinal rule of statutory construction that, when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it is taken." *Air Wisconsin Airlines Corp. v. Hoeper*, 571 U.S. 237, 248 (2014) (brackets omitted). The same principle applies to statutory amendments: "[t]he normal rule of statutory construction is that if Congress intends for legislation to change the interpretation of a judicially created concept, it makes that intent specific." *Midatlantic Nat'l Bank v. N.J. Dep't of Envtl. Prot.*, 474 U.S. 494 (1986); *accord United States v. Reorganized CF&I Fabricators of Utah, Inc.*, 518 U.S. 213, 221 (1996).

That principle is at its strongest when the relevant interpretation came from this Court, which authoritatively settles the meaning of federal statutes. "When Congress intends to" change the meaning of statutory language that this Court has construed, "it ordinarily provides a relatively clear indication of its intent in the text of the amended provision." *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S. Ct. 1514, 1520 (2017). As the treatise cited to support that proposition explains, "[a] clear, authori-

tative judicial holding on the meaning of a particular provision should not be cast in doubt and subjected to challenge whenever a related though not utterly inconsistent provision is adopted," even if the new provision is "in the same statute." *Id.* (quoting Antonin Scalia & Bryan A. Garner, *Reading Law* 331 (2012)). "Legislative revision of law clearly established by judicial opinion ought to be by express language or unavoidably implied contradiction. We know of no case to the contrary." Scalia & Garner 331.

2. That rule controls here. By the time of the AIA, Congress understood that—as Helsinn acknowledged below (C.A. Br. 41)—"on sale" had become a "term of art," and its "established" meaning included non-public sales. Yet Congress left the bar's language intact.

Had Congress meant to change its established meaning as Helsinn suggests, it had several obvious ways to do so that would have tracked the surrounding bars ("*patented*," "described in a printed *publication*," or in "*public* use"). It could have said:

- "*publicly* on sale";
- "on sale *publicly*"; or
- "on sale *to the public*"

Congress's failure to do any of this—or to define "on sale" as meaning "publicly on sale"—confirms that it left the longstanding interpretation of "on sale" intact.

"Congress generally acts intentionally when it uses particular language in one [part] of a statute but omits it in another," particularly where, as here,

"Congress used" the disparate terms "in close proximity—indeed, in the same sentence"—and "repeatedly." *Dep't of Homeland Sec. v. MacLean*, 135 S. Ct. 913, 919 (2015)) (citations omitted). That "make[s] Congress's choice" not to combine "public" and "on sale" here "seem quite deliberate." *Id.* Any other conclusion is "simply contrary to any reasonable interpretation of the text." *Id.* at 920 (citation omitted).

In short, there is no basis to the government's suggestion that the on-sale bar has *always* contained a public-availability requirement, such that the AIA simply ratified that view. U.S. Br. 18-20. (Helsinn makes no such argument. Helsinn Br. 40 n.8.) And as the Federal Circuit observed, if Congress intended "a sweeping change" to the law, "it would do so by clear language" not found in the AIA. Pet. App. 43a.

C. Congress retained the term of art "on sale" and did not indirectly change its meaning.

Helsinn nonetheless contends that the AIA dramatically changed the meaning of the on-sale bar—not directly, but with a carom shot. According to Helsinn, Congress's adoption of a *new* category of invalidating prior art—inventions "otherwise available to the public"—requires reinterpreting the *existing* ones by limiting *all* of them to matters "available to the public."

But "[f]undamental changes in the scope of a statute are not typically accomplished with so subtle a move." *Kellogg Brown & Root Servs., Inc. v. United States ex rel. Carter*, 135 S. Ct. 1970, 1977 (2015). Instead, the "otherwise available to the public"

phrase creates a new category of prior art that prevents patentees from claiming knowledge that is already in the public domain. For example, before the AIA, an *oral* presentation was not prior art even if it disclosed the invention publicly and in detail. *In re Klopfenstein*, 380 F.3d 1345, 1349 n.4 (Fed Cir. 2004). Indeed, the government acknowledges (at 18) that this was the "most obvious purpose" of the new category. That is quite enough to justify the phrase as written; there is no need to stretch the language to give it *more* to do.

1. In attempting to show otherwise, Helsinn now acknowledges (at 38) that under the rule of the last antecedent, the phrase "to the public" does not literally modify "on sale," or anything else in the sentence except "otherwise available." That appears to be a retreat from its previous position that "otherwise available" is a full-blown "series modifier" restricting the preceding series to public activities. Pet. 15–16; C.A. Br. 34-36. Helsinn may have backtracked because reading "otherwise available" as a series modifier creates glaring redundancies, such as inventions "in public use ... available to the public." See Pet. App. 9a n.2 (O'Malley, J., concurring). And as Helsinn's own authority holds, to be a series modifier a phrase must "appl[y] as much to the first and other words [in the series] as to the last." *Paroline*, 572 U.S. 434, 447 (2014) (citation omitted).[6]

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[6] Helsinn seems to think that "otherwise available to the public" affects only the third and fourth terms in the series. *See* Br. 18. That kind of mental gymnastics only confirms that Section 102(a)'s catchall phrase is not a series modifier. Carrying the modifier across the entire list is such a "heavy lift," *Lock-*

Ultimately, Helsinn says that the "otherwise available" phrase does not actually *modify* (in the grammatical sense) anything in the pre-existing statute, but that it merely "inform[s]" the on-sale bar's meaning. Br. 4, 19, 36, 37, 38, 42. But the meaning of "on sale" is settled by two centuries of decisions; it does not need "informing" by a new statutory neighbor. Thus, Helsinn must offer some compelling reason to reinterpret a term of art that Congress declined to change directly—something Helsinn cannot do.

2. Helsinn next contends that "on sale" must be reinterpreted because if it means what it always has, the word "otherwise" would serve no function. Br. 39. Not so. The word "otherwise," which means "in a different way or manner" (Helsinn Br. 19 (citing *Webster's Collegiate* 879)), serves to acknowledge the obvious, but incomplete, overlap between the new category and the old ones, and to clarify that the catchall category captures methods of public disclosure not previously described.

Without the word "otherwise," the statute would read: "A person shall be entitled to a patent unless ... the claimed invention was patented, described in a printed publication, or in public use, on sale, or ~~otherwise~~ available to the public before the effective filing date of the claimed invention[.]" That would ignore the overlap between the catchall phrase and the other settled terms in the list—potentially creating needless confusion by implying, for example, that printed publications are not available to the public, which of course they always have been.

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hart v. *United States*, 136 S. Ct. 958, 963 (2016), that Helsinn must lop off the front half of the list.

The notion that "otherwise" (or its variants) *must* reshape the meaning of preceding words ignores common usage. For instance, saying "I'd like to go see the Astros, the Dodgers, the Red Sox, the Orioles, or any other first-place team" does not imply that the Orioles are in first place (they are not). It means the speaker is willing to see the Orioles in addition to the identified first-place teams and other first-place teams captured by the catchall. Indeed, because "patents," "printed publications," and "public use" *already* connote availability to the public, the proper analogy would be: "I'd like to go see the *first-place* Astros, the *first-place* Dodgers, the *first-place* Red Sox, the Orioles, or any other *first-place* team."

Or take this Court's example in *Barnhart v. Thomas*, 540 U.S. 20 (2003)—parents who warn their son: "'You will be punished if you throw a party or engage in any other activity that damages the house.'" *Id.* at 27. If the son held a party but the house suffered no damage, the Court noted, he "should hardly be able to avoid punishment," as the parents had "proscribed (1) a party, and (2) any other activity that damages the house," and their "reasons for prohibiting the home-alone party may have had nothing to do with damage to the house." *Id.* As in *Barnhart*, Congress's reasons for starting the clock when an invention goes "on sale" "had nothing to do with" public *disclosure*. Congress was concerned with commercialization and extended monopolies, pp. 5-8, *supra*, and it chose to place the on-sale bar in Section 102 even though being "on sale," unlike the other invalidity grounds, does *not* inherently require public availability. *See, e.g.*, *MacLean*, 135 S. Ct. at 919. As *Barnhart*'s illustration shows, adding the catchall

did not override that decision and change "on sale" into "on sale to the public."

3. Aware that "otherwise" is not enough to redefine "on-sale," Helsinn invokes the *noscitur a sociis* canon, under which "words in a statute are 'known by the company they keep.'" Br. 20 (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995)) (alterations omitted). But *noscitur a sociis* applies only when choosing between two possible meanings of an "ambiguous term." *United States v. Stevens*, 559 U.S. 460, 474 (2010). It cannot distort the ordinary definition of an unambiguous term, or unsettle the settled meaning of a term of art, to "create ambiguity when the statute's text and structure suggest none." *Ali*, 552 U.S. at 227; *see also, e.g.*, 2A *Sutherland Statutory Construction* § 47:16 (7th ed. 2018) (*noscitur a sociis* "clarif[ies] the meaning of doubtful words" and "does not apply absent ambiguity"). Helsinn seeks to use *noscitur a sociis* not to resolve ambiguity in the meaning of "on sale," but to *change* the phrase's meaning by imposing a public-disclosure limitation that has no basis in any ordinary understanding of the phrase.

Even if there were ambiguity for *noscitur a sociis* to resolve, that canon reflects the assumption that Congress has listed various items together because they share a "related meaning." *S.D. Warren Co. v. Me. Bd. of Envtl. Prot.*, 547 U.S. 370, 378 (2006). That assumption is unwarranted here.

First, Congress did not adopt the various Section 102(a) bars all at once. The other bars had already acquired their own settled independent meanings long before the AIA. Insofar as words are known by the company they keep, the phrase "otherwise avail-

able to the public" was late to the party—too late to upset the other terms' meanings.

Second, not every statutory list toes a single line, and *noscitur a sociis* therefore is "not an invariable rule." *Russell Motor Car Co. v. United States*, 261 U.S. 514, 519 (1923). One word in a list "may have a character of its own not to be submerged by its association." *Id.* For example, this Court has refused to apply the canon where a statute provides a "disjunctive" list of items that are "each quite distinct from the other no matter how construed." *Graham Cty.*, 559 U.S. at 288. That is the situation here.

As Judge Hand recognized, the on-sale bar restricts "competitive exploitation" of an invention for "quite different reasons" than do the elements of Section 102 that consider a prior "contribution ... to the art." *Metallizing*, 153 F.2d at 520. The former "confin[es] the duration of the monopoly to the statutory term"; the latter "exclud[es] ideas that are in the public domain from patent protection." *Pfaff*, 525 U.S. at 64. Accordingly, Section 102 has long included several bars that either expressly or inherently turn on what is "public," and one—the on-sale bar—that decidedly does not. The Court should not "'rob' any one of [the statutory bars] 'of its independent and ordinary significance.'" *Graham Cty.*, 559 U.S. at 288 (citation omitted).

4. For similar reasons, Helsinn's reliance on *Federal Maritime Commission v. Seatrain Lines, Inc.*, 411 U.S. 726 (1973), and *Paroline* is misplaced. In both cases Congress created the entire list at once, so it made more sense to read the items on the list consistently with the catchall provision that followed. That makes little sense here, where the items in the

list were added at different times and have taken on settled, independent meanings. It would dramatically weaken Congress's ability to add a new catchall category to close a statutory gap if such an addition *necessarily* upset the meaning of preexisting terms by reverberating back up the list.

As noted above, moreover, unlike the lists in *Seatrain* and *Paroline*, the catchall provision in Section 102(a) does not "appl[y] as much to the first and other words as to the last." *Paroline*, 572 U.S. at 447 (citation omitted). In *Paroline*, the statute listed five specific "categories of covered losses"—for example, "certain medical services" and "physical and occupational therapy"—and a sixth catchall category for "any other losses suffered by the victim as a proximate result of the offense." 572 U.S. at 446. Because none of the specific categories included a proximate-cause requirement, it made more sense to read the catchall category to impose that requirement on the list.

Likewise, in *Seatrain*, the statute listed six specific types of "agreements" between competitors—for example, agreements "fixing or regulating transportation rates or fares"—and a catchall category covering agreements "in any manner providing for an exclusive, preferential, or cooperative working arrangement." 411 U.S. at 732. Because all six categories could be read as limited to agreements forming "working arrangement[s]," it made more sense to read the catchall as "summariz[ing] the types of agreements covered," and excluding "one time, discrete transactions" from the statute. *Id.* at 734 (citation omitted). Here, by contrast, applying the catchall to every item in the list would create hope-

less redundancies—such as "in public use ... available to the public."

Aware of this difficulty, Helsinn says prior cases created "ambiguity about the scope of the public-use bar" by treating as public "some uses that did not disclose the claimed inventions to the public," and "the AIA eliminated that ambiguity." Br. 43. As an initial matter, the "otherwise available to the public" language cannot have been drafted to clarify "public use" (or "on sale"), because it was added to a draft of the statute at a time when it included neither "public use" nor "on sale." *See* p. 10, *supra*. And even if Congress thought the meaning of "public use" was unclear, using the catchall to fix it would create a different problem—the catchall would modify different preexisting categories differently. *See Paroline*, 572 U.S. at 447 (a clause is not a series-modifier where not "applicable as much to the first and other words [in the preceding series] as to the last" (citation omitted)); *cf. Lockhart*, 136 S. Ct. at 963 (a clause is not a series-modifier where "it takes more than a little mental energy to process the individual entries in the list, making it a heavy lift to carry the modifier across them all").

Making matters worse, Helsinn's interpretation would in substance read several categories out of the statute, in violation of the "cardinal principle" that "courts must give effect, if possible, to every clause and word of a statute." *Loughrin v. United States*, 134 S. Ct. 2384, 2390 (2014) (citation and internal quotation mark omitted). Under Helsinn's theory, a litigant seeking to prove that a particular invention was "in public use, on sale, or otherwise available to the public" could seek to prove: (1) that the matter is

both "available to the public" *and* in "public use"; (2) that the matter is *both* "available to the public" *and* "on sale" (which includes proving the often-contentious "ready for patenting" element); or (3) *only* that the matter is "available to the public." There would be no reason for litigants ever to accept the burden of proving "public availability" *and* something else—they could prevail by proving public availability alone. Interpreting the catchall category as filling a statutory gap rather than informing the meaning of the other listed bars avoids this problem.

D. Congress's treatment of "public" disclosures in the AIA confirms that it did not upset the meaning of "on sale."

Section 102(a)'s "place in the overall statutory scheme" confirms that Congress did not indirectly revise the scope of the on-sale bar. *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) (citation omitted). In very next subsection, 35 U.S.C. § 102(b), Congress provided a grace period for "[a] disclosure made 1 year or less before the effective filing date of a claimed invention," if one of two conditions is satisfied:

> (A) the *disclosure* was made by the inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor; or
>
> (B) the subject matter disclosed had, before such *disclosure*, been *publicly disclosed* by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor.

35 U.S.C. § 102(b)(1) (emphasis added).

A "disclosure" in Section 102(b) is one of the items referred to in Section 102(a), including a patent, printed publication, or sale. And according to Helsinn, every one of those "disclosures" is necessarily public. But Section 102(b)(1)(B) distinguishes between "disclosure[s]" generally and "public[] disclos[ures]." Helsinn's interpretation thus reads "publicly" out of the statute, again violating the "cardinal principle" that "courts must give effect, if possible, to every clause and word." *Loughrin*, 134 S. Ct. at 2390 (citation and internal quotation mark omitted). Under this Court's longstanding interpretation of the on-sale bar, by contrast, there is no surplusage: some non-public disclosures would fall within Section 102(a) and (b)(1)(A), but only public disclosures would fall within Section 102(b)(1)(B).

This view of the interplay between Sections 102(a) and (b) is also consistent with their drafting history. The Smith amendment that would have stricken the on-sale and public-use bars also would have inserted "to the public" after "disclosure" in the first sentence of Section 102(b)(1), making all Section 102(b) disclosures public and eliminating any surplusage. P. 12, *supra*. But the Lofgren amendment struck both aspects of the Smith amendment (*Markup* 101-102)—confirming that some Section 102(a) disclosures are *not* public.

The government ignores Section 102(b) entirely. Helsinn, by contrast, declares that Section 102(b)(1)(B) refers to "an earlier disclosure of the 'subject matter' that is ultimately included in a later Section 102(a)(1)-qualifying disclosure," and that the "word 'publicly' ... ma[kes] clear that the earlier dis-

closure of the subject matter, like the later disclosure, must be public." Br. 45. Helsinn is correct that Section 102(b)(1)(B) envisions two disclosures, one earlier than the other. But Helsinn cannot explain why Congress needed to clarify that the earlier disclosure must be "public" if *all* Section 102(a) disclosures are *necessarily* public. Put differently, if "disclosure" necessarily implies "public disclosure," as Helsinn insists, then Congress had no need to say "publicly disclosed" in Section 102(b)(1)(B). But Congress did so, further confirming that Congress meant to preserve the on-sale bar's settled meaning.

E. The statute's drafting history shows that Congress intended to preserve the on-sale bar's established meaning.

After ignoring the plain, historically established meaning of "on sale" and doing what it can with the catchall added in 2011, Helsinn turns to the legislative history—especially a series of floor statements by Senator Kyl. Insofar as the Court finds legislative history illuminating, the full history disproves Helsinn's reading. Helsinn's sources are a *post hoc* concoction of statements made after the speaker had failed to change the text.

During the AIA's multi-year drafting process, numerous bills and amendments were introduced, most by Senator Kyl and Representative Smith, that would have done what Helsinn urges here: repeal the on-sale bar in favor of a general public-disclosure standard. Congress rejected that approach and enacted the language at issue here.

Tellingly, Senator Kyl repeatedly *criticized* the language ultimately adopted for *preserving* the exist-

ing understanding of the on-sale bar. Only after losing his fight to repeal the on-sale bar did he attempt to accomplish through the *Congressional Record* what he failed to accomplish in the AIA itself. This Court has repeatedly rejected such "strategic manipulations of legislative history to secure results [Members] were unable to achieve through the statutory text." *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005).

1. The AIA's drafting history shows Congress's understanding that a bill that included the on-sale bar would preserve its well-established meaning. As discussed above (pp. 9-12, *supra*), the relevant provision evolved as follows:

2005/ 2006 "(1) the claimed invention was patented, described in a printed publication, *or otherwise publicly known*" (H.R. 2795, 109th Cong. (2005); S. 3818, 109th Cong. (2006))

[redacted]

2008/ 2009 "(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, *or otherwise available to the public*" (S. 1145, 110th Cong. (2008); S. 515, 111th Cong. (2009))

[redacted]

2011 (AIA)	**"(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention" (H.R. 1249, 112th Cong. (2011))**

In several important ways, this drafting history confirms that the new catchall category of prior art was not intended to modify the on-sale bar. First, it shows that the new category could not have been written to modify (or "inform") the on-sale bar, because it was first proposed in 2005 and 2006 bills that *did not even include the on-sale bar*. The 2007 House bill, by contrast, included the on-sale bar but no catchall provision, and thus was unquestionably written to preserve the bar's settled meaning. Indeed, the House Judiciary Committee recognized that the phrase "on sale" has "been interpreted by the courts," and (thus interpreted) retained the vital policy role of "preventing inventors from extending their monopoly" even in a "first-to-file system." H.R. Rep. No. 110-314, at 57.

In the 2008 Senate bill, the features of the 2005 through 2008 bills were combined to form a bill that *both* added the new catchall provision *and* retained the on-sale bar. The 2008 bill thus captured the key features of both prior bills: the catchall prior-art category that did not modify the on-sale bar, and the pre-existing on-sale bar.

Second, the fixed meaning of "on sale" is confirmed by competing bills in 2008 and 2009 that alternately did, or did not, replace the on-sale bar with a general

public-availability standard. If the claimed invention is only "on sale" under the AIA if the invention is "available to the public," then there would be no difference between:

> (1) barring a patent if the claimed invention were "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public" (S. 1145, 110th Cong. § 2(b)(1) (2008)), and
>
> (2) barring a patent if the invention is "patented, described in a printed publication, or otherwise made available to the public" (S. 3600, 110th Cong. § 2(b)(1) (2008)).

The disagreement concerning which formulation to use confirms that they are different.

Third, contemporaneous statements of Senators and Representatives confirm that even those who opposed retaining the "on sale" language understood that keeping it meant keeping its existing meaning. Senator Kyl objected to the language that ultimately became the AIA because it retains "patent-forfeiture provisions that apply only to non-public prior art." S. Rep. No. 111-18, at 60. Thus, he proposed two different bills that *removed* the on-sale and public-use bars. S. 3600, 110th Cong. § 2(b)(1); S. 610, 111th Cong. § 2(b)(1).

According to Senator Kyl, these bills sought to "*significant*[*ly*] *change*" the language ultimately adopted by "eliminating confidential sales and other secret activities as grounds for invalidity and imposing a general standard of public availability." 154 Cong. Rec. 22,631 (statement of Sen. Kyl). Similarly,

in the House Judiciary Committee, Representative Lofgren successfully opposed an attempt to strike the on-sale and public-use bars because a "range of stakeholders" had "strenuous[ly]" objected to "the deletion of *specific categories of prior art with well established meanings in case law*." *Markup* 102 (emphasis added).

Thus, throughout the AIA's drafting process, there was strenuous debate about *whether* to retain the pre-existing meaning of the on-sale bar, but general *agreement* that, if the on-sale bar remained, it retained that pre-existing meaning.

2. Helsinn ignores this drafting history, citing Senator Kyl's lengthy floor statement made shortly before the AIA passed. Br. 27-28. But "[t]his is a good example of why floor statements by individual legislators rank among the least illuminating forms of legislative history." *SW Gen.*, 137 S. Ct. at 943.

Throughout the drafting process, Senator Kyl repeatedly urged Congress *not* to adopt the language that became the AIA because it *preserved* the existing meaning of the on-sale and public-use bars. Having failed, he abruptly changed course, arguing that the language to which he had repeatedly objected actually *abandoned* the settled meaning of the on-sale bar and—*voilà*—created his preferred "uniform test" of public availability. 157 Cong. Rec. 3,423-24 (2011). In short, Senator Kyl's floor statement does not even reflect *his own* reading of the statute.

Helsinn dismisses the failure of bills that would have enacted Senator Kyl's position by characterizing that position (at 30) as going to "*which* sales trigger the AIA's on-sale bar," not whether "[t]he AIA

eliminated the on-sale bar." But Helsinn's interpretation would achieve the same result.

Under Helsinn's view, the AIA makes proof that an invention was "on sale" under the pre-AIA standard *both* unnecessary *and* insufficient. If a given transaction makes the invention "available to the public," then it is disqualifying prior art *regardless* of whether it satisfies the pre-AIA standard for a commercial sale. And if a given transaction does *not* make the invention "available to the public," then it is *not* disqualifying prior art, even if it *does* meet the pre-AIA standard for a commercial sale. In other words, Helsinn's position would "eliminat[e] confidential sales and other secret activities as grounds for invalidity and impos[e] a general standard of public availability"—precisely what Senator Kyl repeatedly proposed and called a "significant change[]" from the language Congress adopted. 154 Cong. Rec. 22,631.[7]

3. Helsinn's isolated statements from committee reports (at 26) cannot overcome the general recognition that the on-sale bar, if retained, would keep its existing meaning. Helsinn's primary statement says only that "secret *collaborative agreements*" are not prior art. S. Rep. No. 110-259, at 39 (2008) (emphasis added). But a "collaborative agreement" is not a

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[7] Helsinn also relies (at 28-29) on statements from Representative Smith and Senator Leahy, made around the time of the AIA's enactment. Representative Smith, like Senator Kyl, had repeatedly tried to replace the on-sale bar with a general public-availability standard. *See* pp. 10-12, *supra*. And Senator Leahy's single floor statement involved the relationship between Section 102(a) and (b). 157 Cong. Rec. 3,415-16 (2011) (statement of Sen. Leahy).

sale (and vice versa); it refers to joint upstream efforts to develop products, not joint downstream efforts to commercialize them.

Helsinn also cites the statement that the "available to the public" language was added "to clarify the broad scope of *relevant* prior art, as well as to emphasize the fact that it must be publicly available." S. Rep. No. 110-259, at 9 (emphasis added); *see also* H.R. Rep. No. 112-98, Pt. 1, at 43 (2011). But this statement does not mention the on-sale bar, and its limitation to *relevant* prior art confirms that a sale need not make every claim limitation public to trigger the bar. Regardless, that statement cannot overcome Congress's consideration and rejection of bills replacing the on-sale bar with a general public-availability inquiry, and its decision to *preserve* the on-sale bar in the statute based on "strenuous" objection to "the deletion of *specific categories of prior art with well established meanings in case law*." *Markup* 102 (statement of Rep. Lofgren) (emphasis added). In sum, "Congress several times considered, but rejected, the very changes to the on-sale bar Helsinn urges ... were actually made." Pet. App. 12a (O'Malley, J., concurring).

F. Helsinn's position would allow patentees to commercialize their inventions for years, and perhaps indefinitely, before seeking patent protection.

The Patent Act has always barred inventors from extending their patent monopoly by commercializing inventions before seeking to patent them. Pp. 5-8, *supra*. As this Court explained in *Pfaff*: "It is a condition upon an inventor's right to a patent that he

shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." 525 U.S. at 68 (quoting *Metallizing*, 153 F.2d at 520).

Helsinn does not dispute that reversal would upend that purpose, allowing inventors to exploit inventions commercially for years before seeking patents. Helsinn simply says the on-sale bar's longstanding purpose is irrelevant in a first-to-file system. Not so. *Pennock* itself was decided under a first-to-file regime. *See* Patent Act of 1793, ch. 11, § 1, 1 Stat. 318 (1793) (tying validity to what was "known or used" as of the patent application's filing date).[8] But as Justice Story explained for that unanimous Court, if an inventor could "hold back from the knowledge of the public the secrets of his invention" even while selling it "publicly," and later "take out a patent," that would "give a premium to those ... least prompt to communicate their discoveries." 27 U.S. at 19.

1. Allowing inventors to seek patents after selling their inventions, whenever those sales do not disclose *every* element, would allow for rampant pre-patenting commercialization—precisely what the on-sale bar has always prevented.

a. Most obviously, Helsinn's interpretation would allow pre-patent commercialization of inventions via nondisclosure agreements—as Helsinn did here. According to Helsinn, inventors can sell their inven-

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[8] The 1793 Act imposed *both* first-to-file *and* first-to-invent requirements. *See id.* § 3. Though the AIA is a pure first-to-file regime, any first-to-file requirement would, on Helsinn's view, incentivize inventors to file quickly to avoid losing the patent.

tions without triggering the on-sale bar, reaping millions, provided the buyers agree not to disclose every limitation of the claimed inventions or sell an embodiment of the invention without a confidentiality agreement.

Although Helsinn sold its invention to just one distributor, nothing would prevent inventors from selling to dozens of distributors who signed confidentiality agreements, or from making *further* sales protected by nondisclosure agreements. Even an invention's ultimate consumers could be required to sign nondisclosure agreements—*e.g.*, in click-wrap licenses for computer software—allowing them, too, to buy inventions in mass-market quantities without triggering the on-sale bar.

b. The problem of pre-patenting commercialization would be particularly acute for patents on methods of manufacturing or performing a service. Patents have never been awarded after sales of products produced using the would-be patented method. For example, the patent in *Pennock* covered an improvement "in the art of *making* leather tubes or hose." 27 U.S. at 14 (emphasis added). In invalidating the patent, the Court stated that, when selling the resulting product, an inventor may not "hold back from the knowledge of the public the secrets of his invention." 27 U.S. at 19; *see Metallizing*, 153 F.2d at 518 (*Pennock* gave no indication that selling the hose "in any way disclosed the process").

In *Metallizing*, Judge Hand cited *Pennock* in holding that selling products made using patented methods triggers the on-sale bar "regardless of how little the public may have learned about the invention." 153 F.2d at 520. As he put it—in reasoning *twice*

endorsed by this Court—the on-sale bar prevents a patentee from "exploit[ing] his discovery competitively after it is ready for patenting; he must content himself with either secrecy, or legal monopoly." *Id.*; *see Pfaff*, 525 U.S. at 68; *Bonito Boats*, 489 U.S. at 149. A contrary holding would allow inventors to "extend the period of his monopoly" by taking advantage of both "a practical monopoly by means of secrecy" and "a later legal monopoly by means of a patent." *Metallizing*, 153 F.2d at 519-20.

The Federal Circuit has consistently followed *Metallizing*, applying the on-sale bar to sales derived from patented methods whether or not those sales disclose the method, because the sales *commercialize the patented process* in the same way that sales of a patented machine would. *E.g.*, *In re Kollar*, 286 F.3d 1326, 1333 (Fed. Cir. 2002).[9] Helsinn's interpretation would reverse this longstanding precedent—legitimizing delayed patents on both methods of manufacturing physical items and methods for providing technical services, like cloud computing, that can be sold without disclosing how the service works. Inventors could protect such methods as trade secrets for years, perhaps decades, making millions, before ultimately claiming patent monopolies.

c. Helsinn's interpretation would also effectively overturn the longstanding rule that "commercial offers for sale" trigger the on-sale bar. *Pfaff*, 525 U.S. at 67; *see Meds. Co.*, 827 F.3d at 1376-77. An *offer* itself will virtually never make an invention "availa-

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[9] *Accord, e.g.*, *Plumtree Software, Inc. v. Datamize, LLC*, 473 F.3d 1152, 1162-63 (Fed. Cir. 2006); *Scaltech*, 269 F.3d at 1328; *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147-48 (Fed. Cir. 1983).

ble to the public." Often, an offer would not even disclose every element *to the potential buyer*. And even if disclosure to the potential buyer (1) were necessary and (2) made the invention "available to the public," the inventor could easily require the buyer to sign a nondisclosure agreement.

2. Helsinn disputes none of this. Instead, it says (at 32) the concerns motivating the on-sale bar simply disappear in a first-to-file system, as inventors will now apply for patents as soon as their inventions are patent-ready. But Helsinn's claim rests on the unrealistic assumption that inventors will always be so concerned about competing patent applications that they will never pursue the extended monopoly—and the associated profit—that the on-sale bar exists to combat.

If an invention is difficult to reverse-engineer, there is no reason to think its inventor will forgo the chance to multiply her earnings by extending her monopoly beyond the patent term. *See* pp. 47-48, *supra*. Many inventions are "easily concealable"; and inventors of such inventions "could keep their process inventions secret for years or even decades and then surface and file a patent application"—"encourag[ing] delay in patenting." Lemley, *Does "Public Use" Mean the Same Thing It Did Last Year?*, 93 Tex. L. Rev. 1119, 1132 (2015). Moreover, such delay "could take an existing industry by surprise because others who developed but did not patent the technology would not be able to use their own secret use as prior art to defeat the patent." *Id.* Indeed, the on-sale bar *only* affects patent applicants who engage in delay, because irrespective of the timing of any sales, the one-year clock does not start until the

invention is ready for patenting. *Pfaff*, 525 U.S. at 67.

As the House Judiciary Committee recognized, the bar serves "very specific policy goals"—including "encouraging inventors to file early for patent protection" and "preventing inventors from extending their monopoly"—and "there is nothing inherent in a first-to-file system that will deter inventors from making use of their inventions as trade secrets and then some time later filing a patent application." H.R. Rep. No. 110-314, at 57. That was also the view of the Court in *Pennock*, which was decided under a first-to-file regime. P. 46, *supra*. By Helsinn's logic, the Court was wrong.

G. The on-sale bar's settled interpretation is consistent with the policies served by other provisions of the AIA.

Contrary to Helsinn and its *amici*, the on-sale bar's longstanding interpretation is fully consistent with the AIA's other provisions.

1. Noting that Congress repealed the on-sale bar's limitation to sales occurring "in this country" (35 U.S.C. § 102(b) (2006)),[10] Helsinn says this change went "hand in hand" with Congress's "clarification that an invalidating sale must make the claimed invention available to the public." Br. 34. But there is nothing inconsistent between extending the on-sale bar to international sales and otherwise leaving its scope intact. As the House Judiciary Committee explained, the geographic limitation was unnecessary "[g]iven advances in communications technology and

[10] This change similarly affected the public-use bar.

transportation" that provide knowledge "about activities in a foreign land." H.R. Rep. No. 110-314, at 57. That logic applies equally to public and non-public sales. After all, "[a]n inventor can both understand and control the timing of the first commercial marketing." *Pfaff*, 525 U.S. at 67.

2. Citing the AIA's creation of a post-grant-review process—a new avenue for challenging patents after issuance—Helsinn says on-sale bar challenges require "onerous discovery" not suited for such proceedings. Br. 35. But challengers who institute post-grant review based on a sale must have the grounds in hand, *without discovery*, when they file their petitions—typically, within nine months after the patent issues—or the PTAB will not institute review. *See* 35 U.S.C. §§ 321(c), 322(a)(3). The related *inter partes* reviews are not time-limited—but are barred from considering on-sale arguments. *See id.* § 311(b). Moreover, the AIA's purpose was far broader than streamlining post-grant proceedings, and "[i]t frustrates ... legislative intent simplistically to assume that *whatever* furthers" one of "the statute's ... objective[s] must be the law." *Norfolk S. Ry. Co. v. Sorrell*, 549 U.S. 158, 171 (2007) (citation omitted).

3. Helsinn's reliance on the law of other countries without an on-sale bar is likewise unpersuasive. True, some countries "require a claimed invention to be available to the public in order to qualify as prior art." Helsinn Br. 33. But the fact that the AIA aligned U.S. patent law with international law in *some* respects does not mean that it did so in *all* respects. The traditional scope of the on-sale bar is fully consistent with a first-to-file system, *see* pp. 49-50, *supra*, and Congress may have wished to move *to-*

ward the international consensus without going all the way. For example, Congress considered removing the on-sale bar in favor of a public prior-art requirement, which would have more substantially aligned the U.S. and foreign patent systems, but ultimately retained the on-sale bar without change. *See* pp. 10-11, *supra*.

4. Finally, several of Helsinn's *amici*—but notably not Helsinn—point to the removal of the phrase "loss of right to patent" from the title of Section 102, so that the title now reads, "Conditions for Patentability; Novelty." Representative Smith, for example, argues that, "[b]y jettisoning the 'loss of right to patent' from new § 102," Congress confined that provision "solely to the question of *novelty* in light of the *prior art*," and not the question of pre-patent commercialization. Smith Amicus Br. 8.

"The title of a statute," however, "cannot limit the plain meaning of the text." *Pa. Dep't of Corr. v. Yeskey*, 524 U.S. 206, 212 (1998) (citation and brackets omitted). The title remained constant through the drafting process even as the substance changed. *E.g.*, H.R. 1908, 110th Cong. § 3(b)(1) (2007) (version lacking the "otherwise" phrase). And despite Representative Smith's best efforts, Congress did not "repeal" the on-sale bar. Smith Amicus Br. 8. Moreover, this Court has not grounded the commercial-exploitation principle in concepts of forfeiture and loss-of-right. The Court first articulated the principle in *Pennock*, which predates the on-sale bar and "loss of right to patent" language. P. 6, *supra*. *See also Consolidated Fruit-Jar*, 94 U.S. at 92, 94-96 (treating an on-sale bar challenge as separate from

an "abandonment to the public" (forfeiture) challenge).

II. Helsinn's sale of the patented pharmaceutical product to its distributor made the invention available to the public.

This Court should affirm even if it were to limit the on-sale bar to offers and sales that make every element later claimed in the patent "available to the public." Because a single commercial sale or offer still suffices, a sale that discloses every element to a member of the interested public—*i.e.*, a likely commercial buyer—makes the invention "available to the public."

Here, Helsinn's sale *did* disclose every element to Helsinn's third-party distributor, MGI, and a distributor like MGI is precisely the member of the public one would expect to purchase a pharmaceutical invention. The government's claim that only sales to "ultimate customers" trigger the on-sale bar is both atextual and unworkable, especially in this context. Indeed, most patients likely have never purchased medication directly from a pharmaceutical company.[11]

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[11] Helsinn does not even attempt to describe a plausible standard for when a sale makes an invention "available to the public," claiming (at 24 n.3) that Teva forfeited this argument. But Teva consistently argued that Helsinn's sale to MGI made the invention available to the public, including at the certiorari stage. *See, e.g.*, Br. in Opp. 16-17; Pet. App. 151a (acknowledging Teva's argument that "MGI is a member of the public"). Helsinn's forfeiture argument rests entirely on the government's amicus brief below, but the government itself does not assert forfei-

A. A sale or offer that discloses the claimed invention to a commercial purchaser makes the invention available to the public.

1. If a sale also had to make the claimed invention "available to the public," then the proper inquiry would be whether a sale or offer discloses the claimed invention to a member of the public one would expect to purchase it. This interpretation gives meaning to both of the key statutory phrases. It retains the focus on commercialization inherent in the phrase "on sale"—*i.e.*, the idea that the invention must have either been sold or offered for sale. *See* pp. 23-24, *supra*. And it requires that any sale or offer disclose the invention to the member of the public one would expect to be the invention's commercial purchaser, hence making the invention "available to the public."

A single commercial sale has always sufficed to trigger the bar, no matter who buys the invention or what the buyer does with it. *See Cons. Fruit-Jar*, 94 U.S. at 94 ("a single instance of sale may ... be fatal to the patent," even if the inventor does not know the purchaser or "what was done with" the products sold); pp. 5-8, *supra*.

It follows that a single sale is no less invalidating even if the buyer signs a non-disclosure agreement. *See Meds. Co.*, 827 F.3d at 1376 ("It is well established ... that a single sale or offer to sell is enough to

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ture—it addresses on the merits whether Helsinn's sale to MGI made the invention "available to the public." U.S. Br. 26-32. Under those circumstances, this Court may affirm based on any ground supported by the record.

bar patentability even if kept secret from the trade." (citation and internal quotation marks omitted)). After all, even a purchaser who does *not* sign a non-disclosure agreement might not discuss the invention with anyone else—for instance, to protect her own interest as an exclusive distributor. And if a non-disclosure agreement made a sale "not count," there would be no stopping point: inventors could sell to broad swathes of the public, as long as every buyer agreed to confidentiality. *See* pp. 46-47, *supra*. Notably, the government does not argue that the existence of a non-disclosure agreement, or the number of sales, is relevant to whether an invention is "available to the public."

2. The government's proposed test—that a "sale or offer for sale makes an invention available to the public when a product embodying the invention could be purchased by its expected ultimate customers," U.S. Br. 26—is divorced from the statute's text, and would be impossible to administer.

a. The government's focus on the "*ultimate* customer" has no basis in either "on sale" or "available to the public." A "sale" is simply the transfer of an item or service in exchange for value. *See* p. 23, *supra*. A manufacturer's sale to a distributor or retailer is as much a "sale" as the retailer's sale to the consumer. *E.g.*, *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 883, 885 (2007) (describing how a manufacturer "refused *to sell* to retailers" unless the retailers adhered to a "minimum *resale* price" (emphases added)). Similarly, an invention is "on sale" if it is "available for purchase" by distributors or retailers, pp. 23-24, *supra*, whether those

buyers plan to resell it to the "ultimate customer" immediately or to stockpile it for the future.

The government's approach would strip any last shred of meaning from the term "on sale." As described above, pp. 30-31, *supra*, holding that "otherwise available to the public" changes the meaning of "on sale" would reduce the on-sale bar to an example of the type of conduct that makes inventions "available to the public." But the government's approach deprives "on sale" of even *that* limited function. In its view, the invention could be repeatedly and publicly sold, for millions of dollars, without ever placing the invention "on sale"—so long as those sales were to retailers or distributors and not "ultimate customers." The government *admits* (at 26) that, on its reading, Apple can sell millions of iPhones to retailers like Walmart without *ever* placing the iPhone "on sale"; only the retailer can place it on sale. That is true *even if every element of the invention is disclosed* to every purchasing retailer and distributor. That approach simply does not account for Congress's retention of the term "on sale."

Even ignoring "on sale," nothing in the phrase "available to the public" suggests that "ultimate customers" are the only members of the public who count. And the government does not contend that *every* member of the public must have access; its test would appear to include a few carefully controlled sales to individual consumers, perhaps as part of a trial. Yet the government's test would *exclude* multimillion-dollar bulk sales to the largest wholesalers and retailers. There is simply no reason that offering to sell an invention to a handful of "ultimate customers" makes the invention "available to the public"

while offering to sell to *every distributor and retailer in the world* does not.

Finally, the government blithely assumes that the ultimate customer will be easy to identify. But as this case illustrates, it will not. Doctors administer Helsinn's injectable pharmaceutical product in hospitals. If not the distributor that buys from Helsinn, is the "ultimate customer" the hospital? The hospital pharmacy? Or the patient?

b. The government justifies its position based on a misplaced concern about unfairly disadvantaging small companies that do not have in-house distribution networks. U.S. Br. 28. But the point is not distribution, but commercialization. The inventor has begun to make money from the product—and shift the risk to someone else—at the first sale, whether to a distributor or a consumer. The primary benefit of selling to a third-party distributor is not avoiding the cost of in-house distribution, but immediately recognizing a profit. Indeed, as the government recognizes (at 31-32), Helsinn sold to MGI largely so that it could use the revenue from the transaction in the final stages of drug development. This benefit is not limited to small companies; even large pharmaceutical companies generally sell to drug distributors, *not* directly to retailers or consumers. *See* HDA Research Found., *HDA Factbook* 3 (87th ed. 2016) (more than 90 percent of pharmaceutical sales are through distributors).

B. Helsinn's sale to its distributor made the invention available to the public.

Under the correct legal framework, Helsinn's sale of its claimed invention to MGI made the invention

"available to the public." That sale undisputedly disclosed every limitation of the claimed invention to MGI. And MGI, a pharmaceutical distributor, is not just a member of the public, but *precisely* the type of customer one would expect to buy a pharmaceutical product from a pharmaceutical company—whereas individual patients rarely buy medicines from the manufacturer. Even if the on-sale bar requires that sales make the invention "available to the public," it must include a sale that discloses every limitation of the claimed invention to the member of the public most likely to purchase it.

The government's claim (at 31-32) that the "relationship between petitioner and MGI was not a traditional buyer-seller relationship" is both wrong and irrelevant. The district court and the Federal Circuit concluded that the agreement between Helsinn and MGI *was* a commercial sale, and Helsinn did not seek certiorari on that issue. Pet. i; p. 13, *supra*. The fact that, as the government notes, sales were contingent on FDA approval makes no difference, as it is well established that sales can be contingent on uncertain future events. *See* Pet. App. 30a-31a; UCC § 2-105(2). Indeed, the Patent Act itself recognizes that sometimes an invention will be sold or offered for sale before FDA approval; that is one reason why sales that facilitate drug development fall into a safe harbor from infringement. *See* 35 U.S.C. § 271(e)(1); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

Helsinn could have sought an investor rather than a buyer. Or it could have collaborated with MGI without making a *sale*—for instance, MGI could have funded $11 million in development costs in exchange

for a share of future profits. But Helsinn opted to fund its development by *selling* its invention, which was then ready for patenting (Pet. App. 43a-52a), to a distributor. Under any conceivable interpretation of the statute, that sale triggered the one-year grace period to seek a patent. Because Helsinn chose to wait, its patent is invalid.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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October 9, 2018

No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.

ON WRIT OF CERTIORARI
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REPLY BRIEF FOR THE PETITIONER

Though one would never know it from respondents' brief, the Leahy-Smith America Invents Act (AIA) worked a sea change in American patent law. Its principal innovation was to replace the first-to-invent system of priority with a first-inventor-to-file regime similar to other major patent systems. A key component of that change was a new definition of prior art. Under that definition, an inventor is entitled to a patent unless "the claimed invention" was "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date" of the patent claims. 35 U.S.C. 102(a)(1). The new catch-all provision at the end of that list informs the meaning of the terms that precede

it, clarifying that a sale qualifies as prior art only if it makes the claimed invention available to the public.

Respondents' effort to oppose that conclusion is most notable for what it does not include. Respondents make no effort to defend, and in fact run away from, the reasoning of the decision below. Respondents do not attempt to explain how their construction of Section 102(a)(1) fits into the broader context of the AIA. And respondents offer no answer to this Court's cases interpreting statutes with strikingly similar catch-all provisions.

Respondents instead argue that Congress was not sufficiently explicit when it amended the pre-AIA on-sale bar. But it is not easy to imagine how Congress could have more clearly conveyed its intended meaning. Every relevant indicator—the text, the structure, the legislative history, and the underlying policy—supports petitioner's interpretation. Respondents' interpretation has only one thing in common with the Federal Circuit's: it badly misconstrues the AIA. The Federal Circuit's judgment should be reversed.

A. The Plain Text Of 35 U.S.C. 102(a)(1) Requires That A Sale Make The Claimed Invention Available To The Public

1. The Catch-All Provision In Section 102(a)(1) Clarifies The Meaning Of 'On Sale'

a. Section 102(a)(1) lists three categories of patent-defeating prior art. The first two are "patented" and "described in a printed publication." The third category of prior art—set off by a comma and the word "or"—is a three-item list. That list consists of enumerated categories, followed by a catch-all category beginning with the word "otherwise." Construing statutes with that structure, this Court has repeatedly relied on the "familiar canon of statutory construction" that each enumerated

item "must be read in light of the final, comprehensive category." *Federal Maritime Commission* v. *Seatrain Lines, Inc.*, 411 U.S. 726, 734 (1973); *Paroline* v. *United States*, 572 U.S. 434, 447 (2014).

Respondents do not identify a single instance in which this Court, construing a similarly structured statute, has reached a different conclusion. That is unsurprising. As petitioner has explained, a term such as "otherwise" "relat[es] to and defin[es]" the language that immediately precedes it. *United States* v. *Standard Brewery*, 251 U.S. 210, 218 (1920). That rule is in line with the plain meaning of the word "otherwise": "in a different way or manner." *Merriam-Webster's Collegiate Dictionary* 879 (11th ed. 2009). And it honors the venerable *noscitur a sociis* canon, under which words in a statute are "known by the company [they] keep[]." *Gustafson* v. *Alloyd Co.*, 513 U.S. 561, 575 (1995).

b. Respondents' efforts to undercut *Seatrain Lines* and *Paroline* (Br. 34-37) cannot withstand scrutiny. Respondents' first argument—that those cases are inapt because, in each instance, "Congress created the entire list [of statutory terms] at once" (Br. 34)—requires little response. It is irrelevant when Congress added various constituent parts to the statute, because the Court's ultimate task is "simply [to] interpret the statute as written." *Arthur Andersen LLP* v. *United States*, 544 U.S. 696, 705 (2005).

Respondents next argue that interpreting the statute in accordance with *Seatrain Lines* and *Paroline* would create "hopeless redundancies" between "in public use" and the catch-all provision. Br. 35-36. As petitioner has explained, however, some courts had interpreted the pre-AIA public-use bar, much like the pre-AIA on-sale bar, to reach uses that did not make claimed inventions available to the public. See Pet. Br. 43 (collecting cases). The catch-

all provision thus makes clear that a public use, like a sale, is prior art only if it satisfies that requirement.

Respondents do not dispute petitioner's interpretation of pre-AIA precedent on the public-use bar. Instead, they assert that Congress could not have added the catch-all provision to clarify "in public use" because it was initially introduced in a draft bill that deleted the phrases "in public use" and "on sale," and that petitioner's interpretation would make the catch-all provision "modify different preexisting categories differently." Br. 36.

Those assertions lack merit. As to the former: it is the final, enacted text that matters. See *Arthur Andersen*, 544 U.S. at 705. And under this Court's approach in *Seatrain Lines* and *Paroline*, the catch-all provision—as it appears in the final, enacted text—informs the meaning of "public use."

As to the latter assertion: respondents misunderstand the structure of the statute. Section 102(a)(1) contains a three-category, disjunctive list. After the second category—"described in a printed publication"—there is a comma, the word "or," and a third category. The third category contains three subcategories: "in public use, on sale, or otherwise available to the public." Because the catch-all phrase falls within the third category, it directly operates only on the two subcategories that precede it. And it operates on each of those subcategories in exactly the same way: *viz.*, by clarifying that uses and sales qualify as prior art only if they make the claimed invention "available to the public."

Respondents further argue that, under petitioner's interpretation, the catch-all provision will "in substance read several categories out of the statute." Br. 36. That is so, they say, because no litigant would ever try to establish the elements of the on-sale bar if it could simply prove that the claimed invention was available to the public and

thus fell within the ambit of the catch-all provision. See Br. 36-37.

As a preliminary matter, respondents' concern would apply equally to both parties' interpretations. Respondents interpret "patented," "described in a printed publication," and "in public use" as "inherently requir[ing] public availability." Br. 32. If that is true, a litigant could potentially proceed under the catch-all provision whenever it is unable to satisfy the specific requirements of any of those enumerated categories—each of which has a relevant body of case law construing it. See, *e.g.*, *Blue Calypso, LLC* v. *Groupon, Inc.*, 815 F.3d 1331, 1347-1351 (Fed. Cir. 2016) (discussing "printed publication" requirement).

In fact, respondents' concern is illusory. As the government explains, "Section 102(a)(1) contemplates two distinct senses in which an invention may be placed in the public domain." U.S. Br. 16. When an invention is "patented" or "described in a printed publication," the inventive *idea*" is placed in the public domain. *Ibid.* By contrast, when an invention is "in public use," it is "the *physical embodiment* of the invention" that has entered the public domain. *Id.* at 17-18. Without retention of "in public use" or "on sale," the statute would simply read: "patented, described in a printed publication, or otherwise available to the public." In that circumstance, the statute might be read to imply that the catch-all provision was limited to alternative means of making the inventive idea—not the physical embodiment of the invention—publicly available. See *Gustafson*, 513 U.S. at 573-575. Congress foreclosed such an argument by including "in public use" and "on sale."

c. Respondents' remaining arguments concerning the catch-all provision lack merit.

Respondents contend that the word "otherwise" "serves to acknowledge the * * * overlap between the

new category and the old ones, and to clarify that the catchall category captures methods of public disclosure not previously described." Br. 31. But that is just a fancy way of saying that "otherwise" does no work. Without "otherwise," there would still be the possibility of overlap between "in public use," "on sale," and "available to the public." And it is self-evident that "available to the public" captures activities other than public uses and sales. See *Loughrin* v. *United States*, 134 S. Ct. 2384, 2390 (2014).

That "otherwise" does no work in respondents' interpretation is reason enough to reject it. But there is a second, more fundamental flaw: respondents refuse to acknowledge any relationship between the catch-all category and the preceding enumerated categories. As this Court has long recognized, a catch-all category not only reaches "other devices not specifically enumerated," *Federal Maritime Board* v. *Isbrandtsen Co.*, 356 U.S. 481, 492 (1958), but "limit[s] * * * the specifically enumerated categories as well," *Seatrain Lines*, 411 U.S. at 734. Accordingly, the enumerated categories "must be read in light of the final, comprehensive category." *Ibid.*

In an effort to avoid the latter function of the catch-all provision, respondents offer two examples. Br. 32. Neither is illuminating. Respondents first posit an individual saying: "I'd like to go see the Astros, the Dodgers, the Red Sox, the Orioles, or any other first-place team." *Ibid.* That example, however, implies the Orioles are not in first place only because the Red Sox and the Orioles are in the same division and thus cannot both be in first. If the individual instead said, "I'd like to go see the Astros, the Dodgers, the Red Sox, *the Brewers*, or any other first-place team," it would indeed imply that each of the listed teams was in first place—at least if the individual were speaking grammatically. See *Paroline*, 572 U.S. at 447; *Seatrain Lines*, 411 U.S. at 734.

Respondents' second example, drawn from *Barnhart* v. *Thomas*, 540 U.S. 20 (2003), is simply a poor fit here. The Court in *Barnhart* posited parents telling a child: "You will be punished if you throw a party or engage in any other activity that damages the house." 540 U.S. at 27. But here, the question is not whether a phrase modifying a proximate antecedent ("any other activity") reaches back and modifies another ("a party"). The rule of the last antecedent is inapplicable here; the relevant question is whether a catch-all category that is *parallel* to preceding enumerated categories informs the meaning of those categories. Under this Court's precedents, the answer to that question is yes. See *Paroline*, 572 U.S. at 447; *Seatrain Lines*, 411 U.S. at 734.

d. Beyond the catch-all provision, the broader structure of Section 102(a)(1) supports petitioner's interpretation under the *noscitur a sociis* canon. Respondents' attacks on that canon (Br. 33-34) miss the mark.

Respondents first argue (Br. 33) that the *noscitur a sociis* canon does not apply because the phrase "on sale" unambiguously does not require public availability. That is manifestly incorrect. As the government explains in its amicus brief, "on sale" "inherently suggests a sale or offer to sell *to the public*." U.S. Br. 15 (emphasis added). At a minimum, the phrase "on sale" is "susceptible of multiple * * * meanings." *United States* v. *Williams*, 553 U.S. 285, 294 (2008). And if that is true, this is the archetypal case in which the *noscitur a sociis* canon can be used to align the phrase with the "neighboring words with which it is associated." *Ibid.*

Respondents next note (Br. 33-34) that Congress adopted the categories of prior art in the AIA's definition at different times. But respondents cite no case in which this Court has refused to apply the *noscitur a sociis* canon for that reason, and petitioner is unaware of any such

case. That is unsurprising; as petitioner has already explained, it is the final, enacted text that matters to the textual analysis. See *Arthur Andersen*, 544 U.S. at 705.

Respondents suggest that Section 102(a)(1) is a "disjunctive list of items that are each quite distinct from the other no matter how construed." Br. 34 (internal quotation marks and citation omitted). Wrong again. Across its three categories, Section 102(a)(1) identifies five types of prior art. Four of the five, according to respondents, "connote availability to the public." Br. 32. And the one that supposedly does not imply public availability—"on sale"—shares a policy rationale with other categories of prior art: namely, "[a] similar reluctance * * * to remove existing knowledge from public use." See *Pfaff* v. *Wells Electronics, Inc.*, 525 U.S. 55, 64 (1998). The on-sale bar thus does not "have a character of its own," so as "not to be submerged by its association" with the other types of prior art in Section 102(a)(1). *Russell Motor Car Co.* v. *United States*, 261 U.S. 514, 519 (1923). The *noscitur a sociis* canon applies with full force to the phrase "on sale" and confirms petitioner's interpretation of it.

2. *Respondents' Reliance On The Doctrine Of Congressional Ratification Lacks Merit*

In response to petitioner's textual argument, respondents make no effort to defend the reasoning of the decision below. And respondents abandon their reliance on the rule of the last antecedent, a key component of their argument until now.

Respondents instead put their eggs in one textual basket. Respondents contend that the phrase "on sale" "had become a term of art" by the time of the AIA, having been construed in various decisions. Br. 25 (internal quotation marks and alterations omitted). And they further contend

that Congress intended to ratify those decisions, and retain that meaning, when it enacted the AIA. See Br. 25-29. The doctrine of congressional ratification has two elements: (1) Congress must "reenact [the relevant statutory language] without change," and (2) the "supposed judicial consensus [must be] so broad and unquestioned that [the Court] must presume Congress knew of and endorsed it." *Jama* v. *Immigration & Customs Enforcement*, 543 U.S. 335, 349 (2005). Respondents cannot satisfy either element.

To begin with, Congress did not reenact the relevant statutory language without change. To the contrary, when it enacted the AIA, Congress made a series of changes that have a substantial effect on the meaning of "on sale." First and foremost, Congress added "otherwise available to the public." But Congress also added the defined term "claimed invention," 35 U.S.C. 100(j), and removed the geographic limitation on the on-sale bar. And it shifted from a first-to-invent system to a first-inventor-to-file system. Because all of those changes bear on the meaning of "on sale," the congressional-ratification doctrine simply does not apply. See, *e.g.*, *Holder* v. *Martinez Gutierrez*, 566 U.S. 583, 593 (2012).

In any event, there was no broad and unquestioned judicial consensus before the AIA that the phrase "on sale" reached sales that did not make inventions available to the public. Respondents' hyperbolic assertion (uncritically parroted by their amici) that their interpretation aligns with "nearly two centuries" of the Court's case law (Br. 6), starting with *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1 (1829), is incorrect. In *Pennock*, the Court considered language in the 1793 Patent Act permitting the patenting of subject matter that was "not known or used before the [patent] application." *Id.* at 18. The Court read that language to mean "not known or used *by the public*, before

the application." *Id.* at 19 (emphasis added). That is because prior art was meant to address a situation in which an inventor "put [the invention] into public use[] or s[old] it for public use before he applie[d] for a patent." *Id.* at 23. *Pennock* thus made clear that the relevant uses and sales were ones that put inventions into the public domain.

The Court's more recent decisions are to the same effect. The Court echoed *Pennock* in *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989), which construed pre-AIA law to "exclude from consideration for patent protection knowledge that is *already available to the public*." *Id.* at 148 (emphasis added). "[O]n sale" thus included any "public sale" that "placed [the invention] in public commerce." *Id.* at 149. Most recently, in *Pfaff*, the Court reiterated that the on-sale bar prevents an inventor from "remov[ing] existing knowledge from public use." 525 U.S. at 64. "For nearly two centuries," therefore, the Court has actually focused on sales that make the claimed inventions available to the public—on the theory that subsequent patents on those inventions would take away what the public already has.

To be sure, as respondents note (Br. 7-9), some lower-court decisions—mostly from the Federal Circuit—stood in tension with the decisions of this Court and seemingly extended the pre-AIA on-sale bar to sales that did not make the claimed inventions available to the public. It is unclear whether those cases were correctly decided in light of the structure of the pre-AIA on-sale bar. See U.S. Br. 15-18. But even if Congress had not made fundamental changes in the AIA that affect the meaning of "on sale," the doctrine of congressional ratification would not apply, because those cases do not give rise to the requisite "broad and unquestioned" "judicial consensus." *Jama*, 543 U.S. at 349.

In a related vein, respondents suggest (Br. 28) that Congress could have changed the meaning of "on sale" in a different—and, to their minds, clearer—way. But even when this Court has definitively interpreted a statute in a certain manner—again, not the case here—Congress can alter that interpretation by providing a "relatively clear indication of its intent in the text of the amended provision." *TC Heartland LLC* v. *Kraft Foods Group Brands LLC*, 137 S. Ct. 1514, 1520 (2017). Congress did just that in the AIA when it added a new catch-all category based on public availability and linked it to the two preceding enumerated subcategories with the word "otherwise." Given the Court's interpretations of other similarly structured statutes, see pp. 2-3, *supra*, Congress's changes to the AIA provide a crystal clear, not just "relatively clear," indication of its intent.

What is more, the hypothetical, "clearer" alternatives respondents propose (Br. 28) are unpersuasive. Two of respondents' alternatives, "on sale publicly" and "publicly on sale," would function differently from the catch-all provision, because they imply only that the *fact* of the sale must be public—not that the sale must put the claimed invention into the public domain. And while respondents' third alternative, "on sale to the public," would affect the meaning of "on sale" in the same way as "otherwise available to the public," it would not also reach new forms of prior art not covered by the existing enumerated categories. The language Congress used is thus fit for purpose: it simultaneously informs the meaning of "on sale" and extends the reach of Section 102(a)(1).

3. Section 102(b)(1) Does Not Support Respondents' Interpretation

Reprising an argument they pressed below, respondents contend (Br. 37-39) that the phrase "public disclosure" in Section 102(b)(1)(B) is "surplusage" under petitioner's interpretation because a "disclosure" in Section 102(b) is necessarily "public" by virtue of Section 102(a)(1). That argument is both confusing and incorrect.

Section 102(b)(1) creates a one-year grace period during which "[a] disclosure * * * of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1)." All agree that "disclosure" in that sentence refers to a "prior art event" under Section 102(a)(1). The grace period in Section 102(b)(1) applies in two separate circumstances. The first is when the disclosure—that is, the Section 102(a)(1) "prior art event"—was made by the inventor. 35 U.S.C. 102(b)(1)(A). The second is when a third party makes the disclosure, as long as "the subject matter disclosed had * * * [*earlier*] been publicly disclosed by the inventor." 35 U.S.C. 102(b)(1)(B).

Respondents suggest that petitioner "cannot explain why Congress needed to clarify that the earlier disclosure must be 'public' if all Section 102(a) disclosures are necessarily public." Br. 39. Petitioner has already done so. See Pet. Br. 44-45. To reprise: Section 102(b)(1) refers to two distinct transmissions of information: (1) "[a] disclosure * * * of a claimed invention" (*i.e.*, the "prior art event"), and (2) a separate, earlier disclosure of "the subject matter [later] disclosed." The statute specifies that "disclosure * * * of a claimed invention" is an act that falls within the ambit of Section 102(a)(1). Such an act is necessarily public under petitioner's interpretation of Section 102(a)(1). But the statute does not specify anything about the earlier disclosure of the "subject matter." Enter "publicly." That word, as it appears in Section 102(b)

(1)(B), makes clear that "the subject matter disclosed" falls within the ambit of the provision only if the earlier disclosure of the subject matter is itself public.

That only makes sense. Suppose that an inventor tells a friend about an invention in private. After that conversation, but before the inventor makes a disclosure that would qualify as prior art under Section 102(a)(1), a third party independently discloses the same invention. Without the word "publicly," the inventor could argue that the third party's disclosure does not constitute prior art (and thus is no impediment to the inventor's obtaining a patent) simply because the inventor had already "disclosed" the "subject matter" to a friend. That, of course, would be inconsistent with Section 102(a)(1). Congress avoided that result by including "publicly" before "disclosed" in Section 102(b)(1)(B).

B. The Legislative History Of The AIA Supports The Plain-Text Interpretation

As petitioner has explained, the legislative history of the AIA demonstrates that Congress intended to make clear that the sale of a claimed invention qualifies as prior art only if it makes the invention available to the public. Respondents largely ignore the authoritative committee reports that manifest that intention. Instead, they invoke a "general recognition," pieced together from the drafting history of bills that Congress abandoned, that Congress did not intend to require that all prior-art sales make a claimed invention publicly available. Br. 44. That is the epitome of "entering a crowded cocktail party and looking over the heads of the guests for one's friends." *Conroy* v. *Aniskoff*, 507 U.S. 511, 519 (1993) (Scalia, J., concurring). To the extent the Court feels moved to consider it, the legislative history supports petitioner's interpretation.

1. As this Court has repeatedly explained, committee reports represent the "considered and collective understanding of those [members of Congress] involved in drafting and studying proposed legislation" and are "the authoritative source for finding the Legislature's intent." *Garcia* v. *United States*, 469 U.S. 70, 76 (1984). Here, the committee reports unambiguously show that Congress intended to eliminate sales that do not make claimed inventions available to the public as prior art.

According to the House Judiciary Committee's report on the bill that became the AIA, the purpose of the catch-all provision was to "emphasize the fact that [prior art] must be publicly accessible." H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. I, at 42-43 & n.20 (2011). The House Report went on to cite Senate floor statements from March 8 and 9, 2011. Those floor statements included Senator Kyl's statement that the catch-all provision "limits all non-patent prior art to that which is available to the public," *ibid.* (citing 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011)), and Senator Leahy's comment that "subsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art," *ibid.* (citing 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011)).

For its part, the Senate Judiciary Committee, which first added the phrase "otherwise available to the public," explained that the catch-all provision was intended to "emphasize the fact that [prior art] must be publicly available." S. Rep. No. 259, 110th Cong., 2d Sess. 9 (2008). And it specified that the catch-all provision was designed to "make clear that secret collaborative agreements, which are not available to the public, are not prior art." *Id.* at 39.

In the face of those reports, respondents offer conspicuously weak answers. In an interpretive move similar to the Federal Circuit's below, respondents discount the House Report because it does not use the words "on sale." Br. 45. But the House Report expresses the overarching intent to "emphasize the fact that [prior art] must be publicly accessible." H.R. Rep. No. 98, *supra*, Pt. I, at 43. And it cites floor statements making clear that "*all* nonpatent prior art," plainly including sales, must make a claimed invention "available to the public." *Id.* at 43 & n.20 (emphasis added).

Respondents further suggest that the "secret collaborative agreements" cited in the Senate Report must refer to something other than the kind of arrangement petitioner had with MGI. S. Rep. No. 259, *supra*, at 39. The text of the report, however, explains precisely what the Senate committee, like the House committee, meant: the catch-all provision was intended to "emphasize the fact that [prior art] must be publicly available." *Id.* at 9.

Respondents are left to argue that the committee reports "cannot overcome" the drafting history of other unenacted bills. See Br. 45. But that gets it exactly backward. This Court has repeatedly noted that committee reports are the most reliable form of legislative history. See, *e.g.*, *Garcia*, 469 U.S. at 76.

2. Instead of meaningfully engaging with the committee reports, respondents meander through the drafting history of unenacted predecessor bills. See Br. 40-43. They observe that Congress considered eliminating the on-sale bar altogether and suggest that, because Congress did not do so, it must have intended to retain the on-sale bar as it existed before the AIA. Far from doing away with the on-sale bar, however, the AIA "preserves the substantial body of law on other aspects of the on-sale bar

while clarifying that a sale must make the claimed invention publicly available in order to qualify as prior art." Pet. Br. 30 (citing Markup of H.R. No. 1249, House Committee on the Judiciary, at 101 (Apr. 14, 2011)). Thus, the AIA's new definition of prior art incorporates elements of established on-sale and public use jurisprudence, such as the "ready for patenting" requirement, *Pfaff*, 525 U.S. at 67, and the "experimental use" exception, *City of Elizabeth* v. *American Nicholson Pavement Co.*, 97 U.S. 126, 135 (1877).

Respondents' drafting-history narrative only bolsters that interpretation. The statement respondents emphasize from Representative Lofgren illustrates the point. In 2011, the House Judiciary Committee (of which Representative Lofgren was a member) considered an amendment that would have replaced "in public use, on sale, or otherwise available to the public" with "otherwise disclosed to the public." Br. 11-12. Representative Lofgren expressed "concern[] about the deletion of specific categories of prior art with well-established meanings in case law." Br. 12, 43. In response, the committee reverted to the previous formulation, which was then enacted. In the House Report, Representative Lofgren offered views on other aspects of the final bill but did not express disagreement with the committee's conclusion that prior art "must be publicly accessible." H.R. Rep. No. 98, *supra*, at 43, 163-65.

3. Respondents' emphasis on certain statements by Senator Kyl years before the AIA's enactment (Br. 11, 41-43) is similarly misguided. Citing Senator Kyl's concern that retaining the phrase "on sale" might not eliminate so-called "secret sales," respondents accuse Senator Kyl of attempting to "create[] his preferred" meaning through his later floor statement. Br. 43. That is wild speculation. It is more likely that Senator Kyl was persuaded by other

legislators who—like both Judiciary Committees in their official reports—took the position that Section 102(a)(1) as enacted achieved that end. See Pet. Br. 7-8, 25-30. Senator Kyl's ambiguous statements, made years before Congress enacted the AIA, are not reliable gauges of congressional intent.

C. The Structure Of The AIA Further Supports The Plain-Text Interpretation

As petitioner has explained, the AIA fundamentally changed the American patent system and brought our Nation's patent laws in line with other major patent systems around the world. Petitioner's interpretation of Section 102(a)(1) is consistent with the broader structure of the AIA; respondents' is not.

Respondents first contend (Br. 49-50) that, under petitioner's interpretation, inventors will keep their inventions secret and pursue profits, rather than seeking a patent monopoly under the first-inventor-to-file system. That prediction is unrealistic. Even if an invention were "easily concealable," see Br. 49, choosing not to file a patent application would present a serious risk under the AIA. Simultaneous (or near-simultaneous) invention is a common phenomenon, because inventors often recognize (and set out to fix) a problem at the same time. An inventor who keeps an invention secret for too long risks losing his patent rights altogether if another inventor identifies the issue and files an earlier patent application. The first-inventor-to-file system thus "encourages the prompt filing of patent applications." S. Rep. No. 259, 110th Cong., 2d Sess. 7 (2008).

Respondents insist that their interpretation would not conflict with the AIA's new post-grant-review procedure, because "challengers who institute post-grant review based on a sale must have the grounds in hand, *without*

discovery." Br. 51. Under respondents' interpretation, however, a party could make a colorable allegation that a secret sale had taken place, but could still need burdensome discovery to substantiate its claim in the face of the patentee's contrary arguments. Such discovery is ill-suited to the expedited nature of post-grant-review proceedings. See 35 U.S.C. 326(a)(5), (6), (11). That is presumably why Congress limited post-grant-review proceedings to patents governed by the AIA and its revised definition of prior art. Congress's adoption of the post-grant-review procedure further underscores why respondents' interpretation cannot be correct.

D. The Plain-Text Interpretation Better Serves The Broader Purposes Of The AIA And The Patent System

Petitioner's interpretation of Section 102(a)(1) is also consistent with the purposes underlying the patent system. In particular, such a requirement preserves the fundamental *quid pro quo* of patent law, promotes predictability in the patent system, and ensures that small inventors are on equal footing with their larger counterparts. Respondents do not address any of those arguments, and the arguments they do make about the purposes of the patent system lack merit.

1. Respondents contend that petitioner's interpretation would flout the purposes of the patent system by leading to "rampant pre-patenting commercialization" through nondisclosure agreements. Br. 46. Those concerns are overblown. To begin with, petitioner has never suggested that a nondisclosure agreement—without more—would necessarily exclude a sale from the on-sale bar. For example, if a company offered a product to all comers but on the condition that purchasers sign non-disclosure agreements, a court could well conclude that the product was "on sale" and "available to the public." That

hypothetical situation, however, is a far cry from petitioner's pre-FDA-approval sale to a single entity, MGI, which is not an ultimate purchaser. See U.S. Br. 26-30. And it raises the question of what "available to the public" means, which is not properly at issue in this case.

Respondents, moreover, concede (Br. 58-59) that certain forms of "pre-patent commercialization"—for example, the funding of development costs in exchange for future profits—would not qualify as prior art even under their construction of the on-sale bar. That is impossible to square with respondents' contention that pre-patent commercialization starts the on-sale clock. This case illustrates the point. In respondents' view, petitioner could have sold a right to future profits in exchange for $11 million in capital without triggering the on-sale bar. But because petitioner obtained the same $11 million by selling a future right to *distribute its product*—if approved by FDA—it made a prior-art sale. See, *e.g.*, Br. 1. That is an absurdly fine distinction. And it shows that Congress had a purpose other than preventing pre-patent commercialization in mind when it included "on sale" in the AIA: namely, to treat sales that make inventions available to the public as prior art.

2. Respondents also contend (Br. 47-48) that petitioner's interpretation would create an effectively unlimited period of exclusivity for process patents. In the case of process patents, however, the AIA provides still further incentive to avoid delay. The AIA dramatically expanded the "prior user rights" defense, which permits an entity that made commercial use of an invention more than one year before another sought a patent on it to continue using the invention without liability for infringement. See 35 U.S.C. 273. Under pre-AIA law, that defense was limited to business-method patents and to the individuals who actually performed the patented method. See 35

U.S.C. 273(a)(3) (1999). Under the AIA, however, the defense is now available to essentially all process patents that are commercially viable and to anyone (or any entity) with control over the individual performing the patented method. See 35 U.S.C. 273(a), (e)(1).

That change directly responds to respondents' concern that, under petitioner's interpretation, parties will have virtually unlimited exclusivity for process patents that are difficult to reverse-engineer. Under the AIA, an inventor has an incentive to patent its process as soon as possible, even if the inventor's use of the process is secret, so that it can extinguish its competitors' prior-user rights.

3. Respondents further contend (Br. 48-49) that petitioner's interpretation would effectively abrogate the rule that an offer for sale can trigger the on-sale bar. That is incorrect. Just as a sale to the public would constitute prior art, so too would an offer of sale to the public—say, in a newspaper advertisement. Such an offer would make the claimed invention "available to the public" in a way that petitioner's sale to a single entity did not.

E. Respondents Have Forfeited Any Argument That Petitioner's Claimed Invention Was Available To The Public

In the district court, respondents argued that petitioner "violated the on-sale bar even under [its] proposed interpretation of the AIA." Pet. App. 151a. After losing in the district court, however, respondents made the strategic decision not to pursue that argument on appeal in the Federal Circuit. They have thus forfeited any argument that the sale to MGI somehow made the claimed invention "available to the public" under the AIA.

Respondents barely even try to rebut that conclusion. In a footnote, respondents contend that they "consistently argued" that petitioner's sale made the invention availa-

ble to the public. Br. 53 n.11. That is flat wrong. Tellingly, the only citations respondents offer in support of that proposition are to the (pre-forfeiture) opinion *of the district court* and their (post-forfeiture) brief in opposition to certiorari *in this Court*. What matters is what happened between those filings—*viz.*, respondents' strategic decision not to pursue that argument *in the Federal Circuit*.

Respondents' contention that petitioner's forfeiture argument "rests entirely" on the government's Federal Circuit brief is frivolous. Br. 53 n.11. Petitioner cited the government's brief merely as evidence that the argument was not in play in the Federal Circuit. See Pet. Br. 24 n.3. After the government filed its brief noting that respondents were not raising the argument, respondents said nothing to refute that contention in further Federal Circuit proceedings—whether in their reply brief or at oral argument. That is because respondents had in fact jettisoned the argument. Respondents may regret that decision now, but it is too late.

Finally, even if the Court were to blow through respondents' forfeiture and reach the merits of their case-specific and fact-bound argument, petitioner should still prevail. Petitioner's sale to a single entity, MGI, did not make the claimed invention "available to the public." MGI was bound to (and did) keep petitioner's proprietary knowledge related to the claimed invention confidential. See Pet. Br. 9. MGI could not do anything with the product embodying the claimed invention until the Food and Drug Administration approved the product and petitioner manufactured it. See *ibid.* And MGI was not the ultimate purchaser of the product. See *ibid.* If those facts were sufficient to make a claimed invention "available to the public," any sale or offer for sale would qualify.

Respondents cannot avoid the public-availability requirement by simply neutering it. Because the AIA requires that a sale make the claimed invention available to the public, and because respondents have forfeited any argument that the sale at issue here satisfied that requirement, this Court should reject the Federal Circuit's now-undefended reasoning and reverse its indefensible judgment.

* * * * *

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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NOVEMBER 2018

No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A., PETITIONER

v.

TEVA PHARMACEUTICALS USA, INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER

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QUESTION PRESENTED

Whether an invention is "on sale" within the meaning of 35 U.S.C. 102(a)(1) when the public cannot obtain physical embodiments of the invention, but the invention is the subject of licensing and distribution agreements whose existence was disclosed to the public.

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BRIEF FOR THE UNITED STATES
AS AMICUS CURIAE SUPPORTING PETITIONER

INTEREST OF THE UNITED STATES

This case presents the question whether petitioner's invention was "on sale" within the meaning of 35 U.S.C. 102(a)(1) at a time when the public could not obtain physical embodiments of the invention, but the invention was the subject of licensing and distribution agreements whose existence had been disclosed to the public. The United States Patent and Trademark Office (USPTO) is responsible for examining all patent applications and for granting and issuing patents when the applicants satisfy the statutory conditions for patentability. 35 U.S.C. 2(a)(1), 131. Several other agencies of the federal government also have strong regulatory interests in the efficacy of the patent system. The United States therefore has a substantial interest in the Court's resolution of the question presented here.

STATEMENT

1. Since 1790, the patent laws have prohibited the issuance of patents for inventions to which the public already has access. See *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 146-149 (1989). Section 102(a)(1) of Title 35 of the United States Code is the current codification of this longstanding principle. Section 102(a)(1) states that "[a] person shall be entitled to a patent unless * * * the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." 35 U.S.C. 102(a)(1). Section 102(b) provides that, under specified circumstances involving disclosures by the inventor, "[a] disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1)." 35 U.S.C. 102(b)(1). In cases like this one, the patentability of an invention therefore turns on whether the invention was placed "on sale" more than one year before the effective filing date of the patent application. This version of Section 102 was enacted in 2011 as part of the Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284.

Section 102(a)(1) contemplates two conceptually distinct ways in which an unpatented invention may be placed in the public domain so as to bar subsequent patenting. An invention is "described in a printed publication" within the meaning of Section 102(a)(1) if the inventive *idea* is disclosed in a sufficiently public way, and in sufficient detail, to enable a person skilled in the art to make or use it. See *Blue Calypso, LLC* v. *Groupon, Inc.*, 815 F.3d 1331, 1348 (Fed. Cir. 2016) ("To qualify as a printed publication, a reference must have been

sufficiently accessible to the public interested in the art.") (citation and internal quotation marks omitted); *In re Antor Media Corp.*, 689 F.3d 1282, 1288-1290 (Fed. Cir. 2012) (explaining that a printed publication must disclose enough information to enable a person of ordinary skill in the art to make or use the invention). That may occur even if no physical embodiment of the invention has ever been produced, let alone made accessible to the public. The inventive idea likewise will have been disclosed to the public if the invention has been patented, since a compliant patent application must "contain a written description of the invention, and of the manner and process of making and using it," that is sufficient "to enable any person skilled in the art * * * to make and use the" invention. 35 U.S.C. 112(a).

The on-sale bar, by contrast, is typically triggered by the public sale, or offering for sale, of *physical embodiments* of the invention. Such sales or offerings can place an invention in the public domain even if they do not enable a person skilled in the art to make or use it. That may occur if the embodiments are not susceptible to the sort of reverse engineering that would enable an expert to discern how the invention works. For purposes of Section 102(a)(1), a public sale or offering therefore can place the invention in the public domain—*i.e.*, make it "available to the public," 35 U.S.C. 102(a)(1)—even if the inventive *idea* remains secret.

The first United States patent law to include an express on-sale bar was the Patent Act of 1836, ch. 357, 5 Stat. 117, which prohibited the patenting of any invention that was "in public use or on sale, with [the inventor's] consent or allowance," when the patent application was filed. *Id.* § 6, 5 Stat. 119; see *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 65 (1998). Congress preserved

the on-sale bar in the Patent Act of 1952, ch. 950, 66 Stat. 792 (35 U.S.C. 1 *et seq.*), prohibiting the patenting of any invention that "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country" more than one year before the date of the patent application. 35 U.S.C. 102(b) (1952). The AIA moved this provision to Section 102(a)(1) and revised some of its text. See 35 U.S.C. 102(a)(1).

2. a. This case involves a dispute over the validity of a patent covering a 0.25 mg dose of palonosetron in a 5 ml solution, an intravenous formulation directed to reducing the likelihood of chemotherapy-induced nausea and vomiting.[1] Pet. App. 19a-20a, 25a, 60a. On January 30, 2003, petitioner filed a provisional patent application covering the 0.25 mg dose, and the Food and Drug Administration (FDA) approved the 0.25 mg dose in July 2003. *Id.* at 25a. In 2013, petitioner applied for and obtained the patent at issue here, which also covers the 0.25 mg dose. *Id.* at 25a, 142a. The parties agree that this patent is subject to the AIA for purposes of this case. See *id.* at 61a. The parties further agree that the application of Section 102(a)(1) to this case turns on whether the 0.25 mg dose was "on sale" before January 30, 2002, *i.e.*, one year before petitioner filed its provisional patent application. *Id.* at 20a & n.1; see 35 U.S.C. 102(b).

b. Petitioner is a family-owned and family-run company with headquarters in Switzerland. Pet. App. 77a. During the period relevant here, petitioner's business

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[1] Four patents covering the 0.25 mg dose of palonosetron were initially at issue in this case, Pet. App. 19a-22a, but petitioner did not seek this Court's review of the court of appeals' invalidity determination with respect to three of those patents, Pet. 10 n.2.

model was to acquire rights to drug products in the early or middle stage of development, develop those products, and then license the developed products out for marketing and distribution. *Id.* at 78a-79a, 114a. In 1998, petitioner purchased the rights to palonosetron, including the existing development research, and began work to further develop palonosetron into a pharmaceutical product. *Id.* at 77a. By early 2000, petitioner was developing two palonosetron formulations, the 0.25 mg dose and a 0.75 mg dose. *Id.* at 22a.

In September 2000, petitioner issued a press release announcing that it was moving forward with the next phase of clinical trials involving the use of palonosetron to prevent chemotherapy-induced nausea and vomiting. J.A. 50. The press release stated that, "[u]pon market approval, Helsinn will be in a position to supply its marketing partners with a finished product ready for distribution." Pet. App. 108a n.26 (citation omitted). Petitioner's goal in licensing out a palonosetron product was to minimize financial risk for the palonosetron project, which had proved much costlier than petitioner had anticipated, and to plan for the future marketing and distribution of the product in the United States if the FDA approved it. *Id.* at 114a. After "conduct[ing] a lengthy and arduous search for a willing 'commercial partner' for the U.S. market," *id.* at 115a (citation omitted), petitioner entered into a supply-and-purchase agreement and a license agreement with MGI Pharma, Inc. (MGI), an oncology-focused pharmaceutical company. *Id.* at 22a-23a, 115a.

The supply-and-purchase agreement "set the stage" for MGI's "future purchase" from petitioner of the two palonosetron doses that petitioner was then testing. Pet. App. 116a. The agreement provided that, if the

FDA approved either dose, petitioner would sell MGI that palonosetron product. *Id.* at 29a. MGI agreed to purchase exclusively from petitioner, and petitioner agreed to supply, MGI's requirements of "Products," which the supply-and-purchase agreement defined as the pharmaceutical preparations of the palonosetron formulation that "will be described in" an official regulatory approval to market the drugs. *Id.* at 119a (citation omitted); JA. 218; see Pet. App. 23a. The supply-and-purchase agreement also described the purchase process that petitioner and MGI would implement if one of the doses received FDA approval. Pet. App. 23a-24a, 118a. The agreement further provided that, if the FDA did not approve either dose, the supply-and-purchase agreement would terminate automatically. *Id.* at 24a.

The supply-and-purchase agreement was subject to the license agreement. Pet. App. 115a-116a. That agreement gave MGI a license to distribute, promote, market, and sell "Products," which the agreement again defined as the pharmaceutical preparations of the palonosetron formulation that "will be described in" an official regulatory approval to market the drugs.[2] *Id.* at 119a (citation omitted); J.A. 59, 214. In return, MGI agreed to make $11 million in upfront payments to petitioner and to pay additional future royalties on any distributions of the palonosetron products in the United States. Pet. App. 23a.

According to one of petitioner's negotiators, "it was quite clear" to MGI that "this was a developmental .... product," which meant that MGI "w[as] not buying a product." Pet. App. 116a (citation omitted). Rather,

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[2] During the proceedings below, the parties agreed that the "products" covered by the license agreement were 0.25 mg and 0.75 mg doses of palonosetron. Pet. App. 23a.

the negotiator testified, MGI was "buying the rights to participate in the development effort to potentially have a product in the future." *Ibid.* (citation omitted).

Consistent with that testimony, the license agreement provided that, as of the date of the agreement, the palonosetron products were "under development" by petitioner in anticipation of a future application for FDA approval. J.A. 69; see Pet. App. 24a. MGI acknowledged in the license agreement that petitioner might interrupt or discontinue its development of the palonosetron products if that development became "commercially unreasonable" or if the results of the clinical trials were unfavorable. *Ibid.* The license agreement also stated that petitioner made "no warranty" that the palonosetron products would obtain FDA approval or "that a Product can be developed and registered." J.A. 69. Petitioner pledged, however, to "use commercially reasonable efforts to complete the development of the Products" and to file a new drug application with the FDA by the end of 2002, provided that the development was satisfactory and that no unforeseen events or additional FDA requests occurred. J.A. 69-70. The license agreement also allowed petitioner to terminate the agreement if the clinical-trial results were unfavorable and the FDA did not approve the sale of either dosage of the product. Pet. App. 24a.

Several provisions of the license agreement contemplated that the parties would work together on the future development, regulation, and patenting of palonosetron products. See J.A. 62-63, 70-72, 74, 105. Petitioner and MGI agreed that, if clinical trials produced unfavorable results, if the FDA denied approval, or if the products' development was interrupted or discontinued, the parties would "meet to discuss and seek an

agreement" on additional development efforts that the parties deemed appropriate, "including the direct performance and funding by MGI of the further development activities deemed necessary for the registration of the Products." J.A. 70.

The parties further agreed that, if the FDA approved one of the palonosetron doses, MGI would serve as petitioner's agent with respect to the new drug application and would manage and carry out all FDA communications and relations on petitioner's behalf, in close coordination with petitioner. J.A. 71-72. MGI further agreed to collaborate with and assist petitioner in obtaining regulatory approvals outside the United States, with petitioner reimbursing MGI for the expenses it incurred in providing such support. J.A. 74. And the parties agreed that MGI would cooperate with petitioner "for the purpose of filing for and obtaining patent extensions and supplementary or complementary protection certificates" of the existing palonosetron patents. J.A. 105.

Both the license agreement and the supply-and-purchase agreement included appendices that described in detail the palonosetron formulations that petitioner had submitted to the FDA. Pet. App. 33a, 119a-120a. Each agreement contained a confidentiality provision that required MGI to "treat as strictly confidential" any information, data, or documents it received under the agreements that were "not generally known to the trade." *Id.* at 120a.

Petitioner and MGI announced the agreements in a joint press release, and MGI reported the agreements in a Securities and Exchange Commission (SEC) filing that included partially redacted copies of both agree-

ments. Pet. App. 23a. The specific formulations covered by the agreements—*i.e.*, the 0.25 mg and 0.75 mg doses—were not publicly disclosed. *Id.* at 24a, 121a. Meanwhile, MGI's initial payments to petitioner helped fund the ongoing clinical trials of the palonosetron doses. *Id.* at 116a.

3. Respondents sought FDA approval to market a generic 0.25 mg palonosetron product, and petitioners sued respondents for infringing the patent at issue here. Pet. App. 26a. In their defense, respondents asserted that the patent was invalid under Section 102(a)(1) because petitioner's agreements with MGI had placed the 0.25 mg dose "on sale" in April 2001. *Id.* at 55a, 151a; see *id.* at 115a. After a bench trial, the district court held that respondents had not proved that the patent was invalid under Section 102(a)(1). *Id.* at 230a.

The district court held that Section 102(a)(1) "requires a public sale or offer for sale of the claimed invention." Pet. App. 164a. The court found that petitioner's agreements with MGI did not meet that standard because "the sale or offer o[f] sale did not make [the] claimed invention available to the public." *Id.* at 180a. The court rejected respondents' contention that the joint press release and SEC filing, which disclosed to the public the existence of the agreements between petitioner and MGI, had placed the invention "on sale" in April 2001. *Ibid.*; see *id.* at 23a, 120a-121a. The court explained that "the post-AIA on-sale bar inquiry is not focused on the public disclosure of the sale or offer for sale; rather, the 'sale' prong of the on-sale bar requires that the sale make the claimed invention available to the public." *Id.* at 180a. Here, the court concluded, respondents had failed to show how the press release or

SEC filing made petitioner's "*claimed invention*, i.e., its palonosetron formulation, available to the public." *Ibid.*

4. The court of appeals reversed, holding that the patent was invalid under Section 102(a)(1). Pet. App. 17a-52a. The court found that "an agreement contracting for the sale of the claimed invention contingent on regulatory approval is still a commercial sale as the commercial community would understand that term." *Id.* at 30a. The court stated that, under the Federal Circuit's precedents, "an invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale is made public," even if "the details of the invention" are not "disclosed in the terms of sale." *Id.* at 40a.

The court of appeals stated that "[a] primary rationale of the on-sale bar is that publicly offering a product for sale that embodies the claimed invention places it in the public domain, regardless of when or whether actual delivery occurs." Pet. App. 40a-41a. The court explained that prior Federal Circuit decisions had "applied the on-sale bar even when there is no delivery, when delivery is set after the critical date, or, even when, upon delivery, members of the public could not ascertain the claimed invention." *Id.* at 42a. The court considered the AIA's legislative history and found "no indication in the floor statements" by individual members of Congress that those members intended to overrule those earlier Federal Circuit rulings. *Ibid.*; see *id.* at 36a-38a. The court therefore concluded that, "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale" in order for Section 102(a)(1) to apply. *Id.* at 43a. The court of appeals found the on-sale bar to be

applicable here because the supply-and-purchase agreement between petitioner and MGI, which was consummated and publicly announced more than one year before petitioner submitted its provisional patent application, "constituted a sale of the claimed invention—the 0.25 mg dose." *Ibid.*; see *id.* at 20a, 24a.

5. a. The court of appeals denied rehearing and rehearing en banc. Pet. App. 1a-2a. Judge O'Malley concurred in the denial of panel rehearing and wrote separately to respond to points raised in petitioner's rehearing petition and in various amicus briefs. *Id.* at 3a-16a. Judge O'Malley described the panel decision as holding only "that the *particular* agreement at issue triggered the on-sale bar, in part—but not exclusively—because it was made public." *Id.* at 5a. She stated that "an offer for sale between a supplier and distributor can trigger the on-sale bar even though the transaction is several steps removed from the consuming public actually acquiring the invention." *Id.* at 15a-16a.

b. Petitioner filed a motion to stay the mandate, which the court of appeals denied in a per curiam order by the panel. Br. in Opp. App. 1-2. The order stated that, "[f]or the reasons set forth in the majority opinion, and in Judge O'Malley's concurrence to the denial of rehearing, the decision is a narrow one." *Id.* at 2.

SUMMARY OF ARGUMENT

I. Under 35 U.S.C. 102(a)(1), a sale or offer to sell must make an invention "available to the public" in order to trigger the on-sale bar.

A. The term "on sale" typically refers to a product that is sold or offered for sale to the public. Within Section 102(a)(1), the three terms that precede "on sale"—"patented," "described in a printed publication," and "in public use"—reinforce that understanding. All three

terms refer to situations in which either the inventive idea or physical embodiments of an invention are placed in the public domain. The phrase "otherwise available to the public," which was added in 2011 as part of the AIA, confirms that an invention is placed "on sale" only when it is made available for purchase by the public. 35 U.S.C. 102(a)(1).

B. Treating the on-sale bar as limited to sales and offers that make an invention "available to the public" is consistent with the balance that the patent laws have traditionally struck. The Court has repeatedly described the on-sale bar as applying to inventions that have been placed on "public sale" or in "public commerce." So understood, the bar has served to prevent use of the patent system to withdraw from public access inventions that had previously entered the public domain. Before the AIA was enacted, the on-sale bar also was sometimes viewed as an incentive to the prompt filing of patent applications. The AIA provided an alternative means to the same end, however, by amending United States patent law so that priority disputes are now resolved in favor of the first inventor to file a patent application.

C. The AIA's legislative history supports the conclusion that a sale or offer for sale triggers Section 102(a)(1)'s on-sale bar only if it makes the invention "available to the public." Both committee reports and floor statements made that point explicitly.

II. The agreements between petitioner and MGI did not make petitioner's invention "available to the public" and therefore did not trigger Section 102(a)(1)'s on-sale bar.

A. The Court should reject respondents' suggestion that, because petitioner sold its invention to MGI and

MGI is a member of the public, the on-sale bar applies. Treating every sale to a third-party distributor as making an invention "available to the public" is inconsistent with Section 102(a)(1)'s text and purposes and would produce untoward results. Among other things, it would produce unwarranted disparities between large, vertically integrated companies that can perform in-house the various steps needed to prepare an invention for public sale, and smaller companies that rely on third-party distributors to disseminate their inventions to the public.

B. The disclosures by petitioner and MGI concerning the existence and general contours of the agreements between them did not trigger the on-sale bar. For purposes of Section 102(a)(1), an invention can enter the public domain either when the *inventive idea* is disclosed with sufficient specificity to enable a person skilled in the art to make and use it, or when *physical embodiments* of the invention are made available for purchase by their ultimate customers. Public disclosure of a *redacted* version of the supply-and-purchase agreement between petitioner and MGI did not have either of those effects.

C. Petitioner's agreements with MGI did not place the invention "on sale" within the meaning of Section 102(a)(1). The agreements initiated a collaborative arrangement that the contracting parties hoped would culminate in sales of the invention to the public. But the contracting parties recognized that various intermediate steps were necessary before any such sales would occur, and that petitioner might ultimately deliver no palonosetron products even to MGI itself if, for example, the FDA did not approve the relevant palonosetron

doses or the ongoing clinical trials produced unfavorable results. Like similar arrangements between corporate subsidiaries in a large organization, the agreements were intended to facilitate future marketing efforts, but they did not make petitioner's invention available to its ultimate purchasers.

ARGUMENT

Under 35 U.S.C. 102, a patent shall not issue for a claimed invention that was "patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before" a date specified in the statute—here, the date one year before petitioner filed its provisional patent application. 35 U.S.C. 102(a)(1); see 35 U.S.C. 102(b). That statutory text establishes that a claimed invention is "on sale" only when a sale or offer for sale makes the invention "available to the public." The agreements between petitioner and MGI for future distribution of palonosetron products, following further development and regulatory approval, did not satisfy that standard because they did not give the public the opportunity to buy any palonosetron drugs.

The public announcements that the agreements had been consummated did not trigger Section 102(a)(1)'s ban on patent issuance. Because the agreements were disclosed to the public only in redacted form, the disclosure did not enable persons skilled in the art to make or use the invention. And while the announcements alerted the public to the existence of the sale, they did not make the invention itself "available to the public." The judgment of the court of appeals should be reversed.

I. AN INVENTION IS "ON SALE" WITHIN THE MEANING OF SECTION 102(A)(1) ONLY WHEN A SALE OR OFFER FOR SALE MAKES THE INVENTION AVAILABLE TO THE PUBLIC

A. The Text Of Section 102(a)(1) Provides That An Invention Is "On Sale" Only When It Is Available To The Public

Section 102(a)(1) prohibits the issuance of a patent when "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before" a date specified in the statute. 35 U.S.C. 102(a)(1); see 35 U.S.C. 102(b). The term "on sale" inherently suggests a sale or offer to sell to the public. Within Section 102(a)(1), that inference is confirmed by the other enumerated bars to patent issuance, and by the residual phrase "otherwise available to the public."

1. The term "on sale" typically refers to a product that is sold or offered for sale to the public. A product is commonly understood to go "on sale" when consumers first have an opportunity to buy it. See, *e.g.*, *The American Heritage Dictionary of the English Language* 1547 (5th ed. 2016) (defining "on sale" to mean "[a]vailable to customers").[3] That natural understanding of "on sale" suggests that an invention goes "on

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[3] See also, *e.g.*, Suryatapa Bhattacharya, *Coca-Cola Serves Its First Alcoholic Drink*, Wall St. J., May 29, 2018, at B3 ("A fizzy lemon-flavored alcoholic drink that went on sale in Japan on Monday marked Coca-Cola Co.'s first fling at selling alcohol in its 132-year history."); Hayley Tsukayama, *Apple's iPad Pro goes on sale Wednesday*, Wash. Post, Nov. 9, 2015, https://www.washingtonpost.com/news/the-switch/wp/2015/11/09/apples-ipad-pro-goes-on-sale-wednesday/?noredirect=on ("Apple on Monday announced that it will begin accepting online orders for the iPad Pro on Wednesday and that the tablet should show up in stores by the end of the

sale" for purposes of Section 102(a)(1) when it first becomes available for sale to the public.

2. The three terms that precede "on sale" in Section 102(a)(1) reinforce that understanding. 35 U.S.C. 102(a)(1). The terms "patented," "described in a printed publication," and "in public use" all identify circumstances that place an invention in the public domain. *Ibid.* Section 102(a)(1) contemplates two distinct senses in which an invention may be placed in the public domain.

First, when a claimed invention is "patented" or "described in a printed publication," the inventive *idea* becomes publicly available. See *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) ("[A] patent must describe the exact scope of an invention and its manufacture * * * to apprise the public of what is still open to them.") (citation omitted); 35 U.S.C. 112(b); *Blue Calypso, LLC* v. *Groupon, Inc.*, 815 F.3d 1331, 1348 (Fed. Cir. 2016) ("To qualify as a printed publication, a reference must have been sufficiently accessible to the public interested in the art.") (citation and internal quotation marks omitted); *In re Antor Media Corp.*, 689 F.3d 1282, 1288-1290 (Fed. Cir. 2012) (explaining that a printed publication must disclose enough information to enable a person of ordinary skill in the art to make or use the invention). Those circumstances make the inventive idea publicly available by giving persons skilled in the art the knowledge required to make and use the invention.

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week."); Diane Cardwell, *The Swamp-Gas Station: Fuel From Landfill Methane Goes on Sale*, N.Y. Times, Oct. 3, 2013, at B9 ("Clean Energy Fuels will announce on Thursday that it has started selling a fuel made of methane from landfills and other waste sources at its more than 40 filling stations in California.").

Respondents have not contended, and the court of appeals did not suggest, that the invention at issue here had been "described in a printed publication" before January 30, 2002. The *unredacted* licensing and supply-and-purchase agreements between petitioner and MGI would have enabled persons skilled in the art to make the invention. The unredacted agreements were not "printed publication[s]," however, because they were shared only between the two contracting parties subject to a duty of confidentiality. See *Blue Calypso*, 815 F.3d at 1348. *Redacted* versions of the agreement were made available to the public in petitioner's SEC filings, and those redacted agreements *were* "printed publications." As a result of the redactions, however, those filings did not describe the invention in sufficient detail to enable a person skilled in the art to make it. See *Antor Media*, 689 F.3d at 1288-1290.

Second, when a claimed invention is "in public use," the public has access to a *physical embodiment* of the invention. See *Egbert* v. *Lippmann*, 104 U.S. 333, 336 (1881) ("If an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, without limitation or restriction, or injunction of secrecy, and it is so used, such use is public."). Placing that physical embodiment "in public use" therefore can preclude the patenting of that invention, even if the inventive idea remains hidden from the public.

This Court has often recognized that "[a] word is given more precise content by the neighboring words with which it is associated." *Life Techs. Corp.* v. *Promega Corp.*, 137 S. Ct. 734, 740 (2017) (quoting *United States* v. *Williams*, 553 U.S. 285, 294 (2008)). The Court relies on this interpretive principle, known as *noscitur a sociis*, "to 'avoid ascribing to one word a

meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress.'" *Yates* v. *United States*, 135 S. Ct. 1074, 1085 (2015) (quoting *Gustafson* v. *Alloyd Co.*, 513 U.S. 561, 575 (1995)). As explained above, the three specific terms that precede "on sale" all describe occurrences that make an invention available to the public, either in inventive concept or in physical form. Cf. Pet. App. 9a n.2 (O'Malley, J., concurring in denial of panel rehearing) ("[E]ach phrase—i.e., 'patented,' 'printed publication,' and 'public use'—recites a disclosure that is necessarily public."). The *noscitur a sociis* canon therefore suggests that the term "on sale" should be construed in the same manner. Cf. *Gustafson*, 513 U.S. at 573-575 (concluding that a statute's reference to "communication" meant "a public communication" because of its inclusion in a list of terms that "refer[red] to documents of wide dissemination").

3. Although United States patent laws have long barred the patenting of inventions that were "on sale" before a specified date, the phrase "or otherwise available to the public" was added to Section 102(a)(1) by the AIA. 35 U.S.C. 102(a)(1). The most obvious purpose of that language was to serve as a catchall, rendering an invention unpatentable if it was "available to the public" before the specified date, even if it was not covered by any of the four enumerated grounds of unpatentability. *Ibid.* In addition to serving that function, however, the new language sheds light on the proper understanding of the preexisting term "on sale." Cf. *United States* v. *Fausto*, 484 U.S. 439, 453 (1988) ("Th[e] classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be

altered by the implications of a later statute."). In particular, the word "otherwise" indicates that the terms preceding the catchall, including the term "on sale," describe ways in which a claimed invention is "available to the public." 35 U.S.C. 102(a)(1); see 10 *The Oxford English Dictionary* 984 (2d ed. 1989) (defining the adverb "otherwise" as "[i]n another way, or in other ways; in a different manner, or by other means; differently"); *American Heritage Dictionary* 1249 ("[i]n another way; differently," "[u]nder other circumstances," "[i]n other respects"); *Webster's Third New International Dictionary of the English Language* 1598 (1986) ("in a different way or manner," "in different circumstances: under other conditions," "in other respects").

In this respect, Section 102(a)(1) is similar to the statute that this Court construed in *Paroline* v. *United States*, 572 U.S. 434 (2014). For purposes of certain restitution awards, that law defined the term "full amount of the victim's losses" to include all costs incurred by the victim that fell into any of six categories. 18 U.S.C. 2259(b)(3). The first five categories enumerated specific types of costs, such as "physical and occupational therapy or rehabilitation" and "lost income," while the sixth category covered "any other losses suffered by the victim as a proximate result of the offense." *Ibid.* The Court recognized that the "broad, final category * * * is most naturally understood as a summary of the type of losses covered—*i.e.*, losses suffered as a proximate result of the offense." *Paroline*, 572 U.S. at 447. The phrase "otherwise available to the public" in Section 102(a)(1) performs a similar function.

Respondents have suggested that, if the phrase "otherwise available to the public" is read to imply that the preceding terms in Section 102(a)(1) require public

availability, the provision as a whole will be redundant. Br. in Opp. 21-23. That is incorrect. Most obviously, that catchall language makes clear that the enumerated categories of prior art are not exclusive. And, to the extent that the phrase "otherwise available to the public" *clarifies* the proper understanding of the preexisting term "on sale," it performs an additional useful function. Congress could not have reliably achieved the same result by deleting the enumerated categories of prior art and drafting Section 102(a)(1) to refer solely to an "invention" that was "available to the public" at a particular point in time. Such a dramatic textual change, including the elimination of an express "on sale" bar that had been part of United States patent law since 1836, might well have been construed as substantially altering prior patentability rules. Cf. *Paroline*, 572 U.S. at 447-448 (explaining that the catchall category of costs did not render the five enumerated categories superfluous because "[t]he first five categories provide guidance to district courts as to the specific types of losses Congress thought would often be the proximate result of a Chapter 110 offense and could as a general matter be included in an award of restitution").[4]

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[4] As respondents point out (Br. in Opp. 28), the phrase "otherwise available to the public" (and close variants of that phrase) first appeared in predecessor bills that did not contain the term "on sale." That sequence of events demonstrates that the phrase was not initially drafted for the purpose of clarifying that an invention is "on sale" only if it is publicly available. The phrase nevertheless serves that purpose as it appears in the version of Section 102 that Congress ultimately enacted.

B. Treating The On-Sale Bar As Limited To Sales And Offers That Make An Invention "Available To The Public" Is Consistent With The Balance That The Patent Laws Have Traditionally Struck

"From their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). In seeking to achieve this "careful balance," *ibid.*, patent law has long restricted inventors' ability to commercially exploit their inventions in the public sphere before making the disclosures necessary to receive patent protection for their ideas. See *Pennock* v. *Dialogue*, 27 U.S. (2 Pet.) 1, 19-24 (1829).

"From the Patent Act of 1790[, ch.7, 1 Stat. 109,] to the present day, the public sale of an unpatented article has acted as a complete bar to federal protection of the idea embodied in the article thus placed in public commerce." *Bonito Boats*, 489 U.S. at 148-149. This Court first recognized the patent laws' focus on "public sale[s]," *id.* at 149, in *Pennock*. There, the Court held that an inventor loses his right to a patent "if he suffers the thing invented to go into public use, or to be publicly sold for use, before he makes application for a patent," because "[h]is voluntary act or acquiescence in the public sale and use is an abandonment of his right." 27 U.S. (2 Pet.) at 23-24. The Court described this doctrine as a carryover from English common law, under which "letters patent were unavailable for the protection of articles in public commerce at the time of the application."

Bonito Boats, 489 U.S. at 149 (citing *Pennock*, 27 U.S. (2 Pet.) at 20).

Congress codified that principle in the Patent Act of 1836 by prohibiting the patenting of any invention that, at the time the application was filed, was "in public use or on sale, with [the inventor's] consent or allowance." § 6, 5 Stat. 119; see *Pfaff* v. *Wells Elecs., Inc.*, 525 U.S. 55, 65 (1998). The legislative history of that statute reflects Congress's concern that then-existing patent laws accorded "no power to the Secretary to refuse a patent for want of either novelty or usefulness." S. Rep. No. 338, 24th Cong., 1st Sess. 2 (1836). That statutory gap had enabled the "reprehensible" practice "of taking out patents for what has been long in public use, and what every one has therefore a right to use." *Id.* at 3-4. That history suggests that, in barring the issuance of patents for inventions that were already "on sale," Congress sought to address sales or offers of sale that had made an invention publicly available.

Congress retained the "on sale" language in subsequent amendments to the patent laws, initially adding a two-year grace period in which the inventor could file an application and later reducing that grace period to one year. *Pfaff*, 525 U.S. at 65. Meanwhile, this Court recognized that the "on sale" bar did not preclude an inventor from patenting an invention when the inventor "does not voluntarily allow others to make it and use it, and so long as it is not on sale for general use." *Elizabeth* v. *Pavement Co.*, 97 U.S. 126, 135 (1878). In contrast, a sale that placed items embodying the invention in the public domain precluded a patent. See *Consolidated Fruit-Jar Co.* v. *Wright*, 94 U.S. 92, 93-94 (1877) (holding that patent for fruit jars was invalid where the inventor sold a dozen or more jars "to get the money

which they yielded, and to test their salability in the market").

The Patent Act of 1952 preserved the bar on patenting inventions that had been "on sale," prohibiting the issuance of patents for any invention that "was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country" more than one year before the date of the patent application. 35 U.S.C. 102(b) (1952). That provision and Section 102(a) of the same statute "operate[d] in tandem to exclude from consideration for patent protection knowledge that is already available to the public," thereby expressing a congressional judgment that patenting such inventions would "injure the public by removing existing knowledge from public use." *Bonito Boats*, 489 U.S. at 148. The Patent Act of 1952 therefore prohibited the patenting of an invention that had been "placed in public commerce" by a "public sale." *Id.* at 149.

Before the AIA was enacted, the Federal Circuit repeatedly held that "[t]he overriding concern of the on-sale bar is an inventor's attempt to commercialize his invention beyond the statutory term." *Atlanta Attachment Co.* v. *Leggett & Platt, Inc.*, 516 F.3d 1361, 1365 (2008); see *Netscape Commc'ns Corp.* v. *Konrad*, 295 F.3d 1315, 1323 (2002) (same); *STX, LLC* v. *Brine, Inc.*, 211 F.3d 588, 590 (2000) (same). Standing alone, that characterization of the on-sale bar's purpose might suggest that the bar is triggered by any transaction from which the inventor makes money on his invention. As explained above, however, this Court's decisions have emphasized the distinct purpose of preserving the public's access to inventions that have already entered the public domain. Congress's addition of the phrase "otherwise available to the public" in the

AIA confirms the primacy of that legislative purpose. 35 U.S.C. 102(a)(1).

That choice was particularly explicable given another feature of the AIA. Before the AIA was enacted, disputes as to priority among competing patent applicants were resolved in favor of the applicant who had first *invented* the invention for which a patent was sought. See *Pfaff*, 525 U.S. at 61 ("[I]t is normally the first inventor to conceive * * * who establishes the right to the patent."). Under that regime, the on-sale bar served in part to prod inventors to seek patents expeditiously, thereby hastening the time at which a patent would expire and the invention would reenter the public domain. Under the AIA, however, priority disputes are resolved in favor of the first inventor to *file a patent application*. See *Madstad Eng'g, Inc.* v. *United States Patent & Trademark Office*, 756 F.3d 1366, 1368 (Fed. Cir. 2014). Congress's addition of language ("otherwise available to the public") confirming that the on-sale bar should be confined to inventions that had previously entered the public domain thus coincided with its enactment of an alternative disincentive to artificial delay in applying for patents.

C. The AIA's Legislative History Supports The Conclusion That A Sale Or Offer For Sale Must Make An Invention "Available To The Public" In Order To Trigger Section 102(a)(1)'s On-Sale Bar

In its favorable report on the AIA, the House Judiciary Committee noted that inclusion of the phrase "available to the public" in proposed Section 102(a)(1) was intended in part "to emphasize the fact that [prior art] must be publicly accessible." H.R. Rep. No. 98, 112th Cong., 1st Sess., Pt. 1, at 43 (2011). An earlier Senate Committee Report on a predecessor bill that contained

the same language had likewise stated that "the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publicly available." S. Rep. No. 259, 110th Cong., 2d Sess. 9 (2008).

In a floor statement on the AIA, Senator Kyl described Section 102(a)(1)'s residual clause as clarifying that the preceding terms, including "on sale," were limited to acts that had made an invention "available to the public." 157 Cong. Rec. 3423 (2011). One of the bill's sponsors, Senator Leahy, expressed similar views, stating that Section 102(a)(1) "imposes an overarching requirement for availability to the public, that is a public disclosure," thereby limiting Section 102(a)(1) "to subject matter meeting the public accessibility standard." *Id.* at 3415. Senator Kyl also emphasized the connection between new Section 102(a)(1)'s express public-availability standard and the AIA's shift from a first-to-invent to a first-inventor-to-file rule of patent priority. See *id.* at 3423-3424. He explained that, "[b]y adopting the first-to-file system, * * * the present bill already provides ample incentive for an inventor to enter the patent system promptly. There is no need to also require forfeiture of patents simply because the inventor has made some use of the invention that has not made the invention available to the public." *Id.* at 3424; see Pet. Br. 27-28.[5]

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[5] With respect to the scope of the Section 102(a)(1) on-sale bar, the legislative history focused significantly on the inadvisability of treating certain "secret" sales or offers to sell as barriers to patent issuance. See Pet. Br. 7, 26, 28. The court of appeals found that this concern was not implicated here because the agreements between petitioner and MGI were disclosed to the public. See Pet. App. 37a-38a. The primary thrust of this aspect of the legislative history,

II. THE AGREEMENTS AT ISSUE IN THIS CASE DID NOT MAKE THE INVENTION "AVAILABLE TO THE PUBLIC" WITHIN THE MEANING OF SECTION 102(A)(1) AND THEREFORE DID NOT TRIGGER THE ON-SALE BAR

A. An Invention Is "On Sale" Within The Meaning Of Section 102(a)(1) Only When A Product Embodying The Invention Can Be Purchased By Its Expected Ultimate Customers

Respondents have suggested that, even if an invention must be "available to the public" in order for the on-sale bar to be triggered, that requirement is satisfied here in part because "MGI is a member of the public." Br. in Opp. 17 (quoting Pet. App. 151a). That is incorrect.

1. A sale or offer for sale makes an invention available to the public when a product embodying the invention could be purchased by its expected ultimate customers. A new model of the iPhone, for example, will be "on sale" when consumers have an opportunity to buy it, not when Apple ships the new iPhones to Walmart so that Walmart can sell them to the public. This paradigmatic understanding of what it means to make an invention "available to the public" comports with this Court's recognition that "[t]he aim of the patent laws is not only that members of the public shall be free to manufacture the product or employ the process disclosed by the expired patent, but also that the consuming public at large

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however was that such secret sales or offers to sell should not preclude patenting of an invention *because* those arrangements do not make an invention publicly available. That concern is directly implicated here, whether or not the relevant sale is properly characterized as "secret." See pp. 30-31, *infra*.

shall receive the benefits of the unrestricted exploitation, by others, of its disclosures." *Scott Paper Co.* v. *Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945); cf. *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111, 122 (1938) ("Sharing in the goodwill of an article unprotected by patent or trade-mark is the exercise of a right possessed by all—and in the free exercise of which the consuming public is deeply interested.").

Although many inventions are intended for ultimate purchase by ordinary individual consumers, the nature and contours of the expected customer base will vary from product to product. Some products (*e.g.*, cash registers or bulldozers) may as a practical matter be purchased only by businesses or by particular types of business; others may be legally available only to persons with a particular license. An inventor who makes his invention available to a purchaser of that character may thereby place his invention "on sale," even if ordinary consumers have no opportunity to buy it.

The fact that the relevant "public" may vary from invention to invention, however, does not mean that the on-sale bar is triggered by *every* commercial sale to a person other than the inventor. Such a rule would have obvious untoward results. It would mean that the on-sale bar is triggered by a secret sale or offer to sell (see pp. 25-26 n.5, *supra*), or by a sale to the inventor's corporate affiliate. If Congress had intended to make the on-sale bar so broadly applicable, it presumably would have used language tailored to that purpose, *e.g.*, by barring the issuance of a patent for an invention that "was sold or offered for sale to any person" before a specified date. And the fact that physical embodiments have been sold or offered for sale to a single entity other than the inventor does not, standing alone, necessarily

implicate Section 102(a)(1)'s core purpose of preventing the withdrawal from public accessibility of inventions that have already entered the public domain.

2. To be sure, third-party distributors like MGI often play an essential role in the overall process by which an invention is made available to its ultimate expected customers and thus is placed "on sale." But treating such a distributor as "the public" would place smaller companies (like petitioner) that require such assistance at an unwarranted disadvantage. Contracts like the supply-and-purchase agreement between petitioner and MGI mirror the arrangements that might occur within a large, vertically integrated company that has the in-house capacity to develop, manufacture, and distribute its own products. Preparatory steps within such a company would not trigger the on-sale bar until the product's expected ultimate purchasers were actually able to buy it. The fact that petitioner enlisted the help of a third-party distributor, rather than performing the same distribution functions in-house, did not cause its invention to become "available to the public" at an earlier date.

3. This Court's decision in *Pfaff* does not support a categorical rule of the sort described above. In *Pfaff*, representatives of Texas Instruments approached an inventor and asked him to develop a new device for mounting and removing semiconductor chip carriers. 525 U.S. at 58. The inventor prepared detailed drawings describing his design, and he showed a sketch of his concept to Texas Instruments. *Ibid.* Texas Instruments made an oral purchase order for 30,100 of the inventor's new sockets and gave the inventor written confirmation of that order in April 1981. *Ibid.* Because of

manufacturing delays, however, the inventor did not fill the order until July 1981. *Ibid.*

The *Pfaff* Court held that the on-sale bar set forth in the Patent Act of 1952, see 35 U.S.C. 102(b) (1994), was triggered when the relevant invention was (a) the subject of a commercial offer for sale, and (b) ready for patenting. 525 U.S. at 67. The Court's focus was on the latter requirement, see *id.* at 60-67, but the Court also concluded that the oral purchase order in that case had placed the invention "on sale" within the meaning of the statute, *id.* at 67.

Because *Pfaff* was decided under the pre-AIA version of the on-sale bar, the Court had no occasion to analyze whether the sale to Texas Instruments made the invention "available to the public" within the meaning of current Section 102(a)(1). In any event, the transaction at issue in *Pfaff* differed substantially from the April 2001 agreements between petitioner and MGI. The invention in *Pfaff* was a socket to mount and remove semiconductor chip carriers, which Texas Instruments presumably intended to use to manufacture its own products. See 525 U.S. at 58. Texas Instruments was thus the ultimate purchaser of the sockets as discrete units of commerce. The contract between the parties, moreover, committed the inventor to provide a specified commercial quantity of sockets, which were delivered approximately three months after the written confirmation of the oral purchase order.

In this case, by contrast, MGI "w[as] not buying a product," but rather was "buying the rights to participate in the development effort to potentially have a product in the future." Pet. App. 116a. The agreements between petitioner and MGI reflected the parties' understanding that it was uncertain whether, when, and in

what quantities petitioner would ultimately deliver palonosetron. See *id.* at 23a-24a. Although the Federal Circuit recognized those uncertainties, the court found it sufficient that the supply-and-purchase agreement would nevertheless qualify as a "contract to sell" under the Uniform Commercial Code. See *id.* at 30a-31a. But given the preliminary and contingent nature of the parties' agreement, that contract did not make petitioner's invention "available to the public," and therefore did not place it "on sale" within the meaning of Section 102(a)(1).

B. Public Disclosure Of The Existence Of The April 2001 Agreements Did Not Trigger The Section 102(a)(1) Bar

The court of appeals stated that "an invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale is made public." Pet. App. 40a; see *id.* at 43a ("conclud[ing] that, after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale"). The court's conclusion that the sale at issue here had been "made public" was based on the fact that the supply-and-purchase agreement between petitioner and MGI "was publicly announced in MGI's 8-K filing with the SEC." *Id.* at 38a. The court thus correctly (though implicitly) recognized that MGI's own status as a member of the "public" was insufficient to trigger the on-sale bar, and that some form of broader public accessibility was required. The court was wrong, however, in concluding that public disclosure of the *sale's existence* made the *invention* "available to the public."

As explained above (see pp. 2-3, 16-17, *supra*), Section 102(a)(1) contemplates two distinct senses in which an invention may be placed in the public domain so as to

preclude subsequent patenting. That may occur if the *inventive idea* is made public, with sufficient specificity to allow persons skilled in the art to make and use it, even if no physical embodiment of the invention yet exists. Or it may occur if *physical embodiments* of the invention become available to their expected ultimate purchasers, even if the idea itself remains secret.

In this case, the joint press release and MGI's SEC filing did not have either of those effects. The redacted version of the supply-and-purchase agreement that was publicly disclosed with the SEC filing did not reveal the inventive idea. And the fact that the sale's existence was publicized has no logical bearing on whether physical embodiments of the invention were made available to potential ultimate purchasers.

C. Petitioner's Agreements With MGI Did Not Make Products Embodying The 0.25 Mg Dose Of Palonosetron Available To The Public

The April 2001 agreements between petitioner and MGI did not place petitioner's invention "on sale" because those agreements did not make the 0.25 mg dose of palonosetron available to the public in its embodied form. Although those agreements "set the stage" for MGI's "future purchase" of palonosetron products, MGI "w[as] not buying a product," but rather was "buying the rights to participate in the development effort to potentially have a product in the future." Pet. App. 116a. The agreements also recognized that the FDA had not yet approved the marketing of the palonosetron drugs described in the agreements, and that such approval would be a prerequisite to any distribution of the drugs to the public. *Id.* at 23a-24a, 29a, 119a. The agreements further acknowledged that petitioner might not sell any palonosetron products to MGI at all

if, for example, the FDA did not approve the relevant palonosetron doses or the results of the ongoing clinical trials were unfavorable. *Id.* at 24a; J.A. 69-70.

The relationship between petitioner and MGI was not a traditional buyer-seller relationship. Rather, the license and supply-and-purchase agreements anticipated that petitioner and MGI would work together on future efforts to develop, regulate, and patent palonosetron products. See J.A. 62-63, 70-72, 74, 105. MGI gave petitioner initial infusions of capital, totaling $11 million, despite the contracting parties' recognition that there might never be a palonosetron product for MGI to purchase. Pet. App. 23a; J.A. 69-71. Petitioner in turn shared the innovative details of the palonosetron formula with MGI, subject to a confidentiality agreement between the parties. Pet. App. 119a-120a.

The April 2001 agreements thus reflected the contracting parties' shared objective that, through the combined efforts of petitioner and MGI, the palonosetron drugs would become available to their expected ultimate purchasers at some indefinite time in the future. The agreements allowed petitioner and MGI to collaborate on development and distribution projects that a larger organization might have handled in-house. But neither the arrangement between petitioner and MGI, nor similar in-house transactions between corporate subsidiaries in a larger, vertically integrated organization, make pre-market products "available to the public." Thus, while a new invention may be subject to intermediate transactions before its commercial marketing to the public, those preparatory transactions by themselves do not place the invention "on sale" within the meaning of Section 102(a)(1).

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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AUGUST 2018

No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF NEITHER PARTY

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INTEREST OF AMICUS CURIAE

The American Intellectual Property Law Association ("AIPLA") is a national bar association of approximately 13,500 members who are primarily lawyers engaged in private and corporate practice, in government service, and in the academic community.[1] AIPLA's members represent a wide and diverse spectrum of individuals, companies, and institutions involved directly and indirectly in the practice of patent, trademark, copyright, trade secret, and unfair competition law as well as other fields of law affecting intellectual property. Our members represent both owners and users of intellectual property. Our mission includes helping establish and maintain fair and effective laws and policies that stimulate and reward invention while balancing the public's interest in healthy competition, reasonable costs, and basic fairness.

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[1] In accordance with Supreme Court Rule 37.6, AIPLA states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than AIPLA and its counsel. Specifically, after reasonable investigation, AIPLA believes that (i) no member of its Board or Amicus Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to the litigation in this matter; (ii) no representative of any party to this litigation participated in the authorship of this brief; and (iii) no one other than AIPLA, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

AIPLA has no stake in any of the parties to this litigation or in the result of this case.

AIPLA has no stake in the parties to this litigation or in the result of this case, other than its interest in the correct and consistent interpretation of the laws affecting intellectual property.[2]

SUMMARY OF ARGUMENT

The Federal Circuit failed to give effect to Congress's recent revisions of the "on sale" provision at 35 U.S.C. §102. Those revisions replaced patent forfeiture for any sale with a prior art effect only for a sale that makes the invention publicly available before a patent application is filed. Congress enacted those revisions as part of the conversion to a "first inventor to file" priority system to bring greater transparency, objectivity, and predictability to the patent system.

Under the 1952 Patent Act, the United States employed a "first to invent" priority system in which the "on sale" doctrine limited an inventor's right to a patent. The "on sale" doctrine required a forfeiture of patent rights if the invention was commercially sold more than a year before the application was filed. Such sales were permitted within a year of filing under a grace period that allowed inventors to determine if their inventions merited patent protection. The potential forfeiture served to

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[2] AIPLA has the consent of the parties to file this amicus brief, pursuant to Supreme Court Rule 37.3(a). Petitioner filed a blanket consent with this Court on August 1, 2018. Respondent consented by counsel via email on August 15, 2018.

incentivize prompt filings of patent applications and to prevent the commercial exploitation of inventions outside of the patent term.

When Congress enacted the America Invents Act ("AIA"), it replaced this "first to invent" system with a "first inventor to file" system to bring U.S. law closer to patent systems around the world. Congress recognized that a first-inventor-to-file system is simpler, more objective, and more transparent than a first-to-invent system.

The first-inventor-to-file system necessarily required revision of the Patent Act, specifically revisions of §102. The purposes of §102, however, remain unchanged: to set out conditions of patentability that ensure the novelty of the claimed invention and its prompt disclosure in a timely-filed application. Congress decided that these purposes are best served by a first-inventor-to-file system. Under that system, a confidential invention date can no longer affect novelty and the incentive for prompt filing is now provided by the risk of losing patent protection to earlier filers.

These revisions to §102 further the AIA's goals of simplicity, objectivity, and transparency. For a sale to be deemed prior art, it must make "the claimed invention" "available to the public." It is not sufficient that the invention was simply the subject of a sale transaction. Patent owners and potential infringers must be able to assess the validity of a patent from publicly available information. With these changes, Congress abandoned the forfeiture model of the former on-sale provision and adopted a model that is based on prior art and that encourages disclosure.

Although the meaning of "available to the public" may need to be developed on a case-by-case basis for different types of inventions, that cannot justify turning a blind eye to Congress's express language. This language requires that, to preclude patentability, a sale must make the "claimed invention" "available to the public." The decision below, however, converts what should be a simple legal issue into a potentially fact-intensive issue in many cases. This would increase the time and expense required for discovery, motion practice, trial, and appellate review of this subjective issue of forfeiture, directly contrary to Congressional intent.

ARGUMENT

I. The Federal Circuit Failed to Enforce the Statutory Requirement That an Inventor's Sale Must Make the "Claimed Invention" Public for Prior Art Effect.

The question presented is: "Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention?" AIPLA respectfully submits that the answer is "no."

This Court should reverse the decision below because the Federal Circuit focused too narrowly on the words "on sale" rather than construing the entire provision at issue, 35 U.S.C. §102. Congress expressly revised §102(a) to require that a public use or sale

make the "claimed invention" publicly available to qualify as prior art. This feature is central to the AIA's purposes of making U.S. law more efficient and predictable, and of harmonizing it with international standards for prior art.

A. Pre-AIA §102 Included "Loss of Right" Forfeiture Provisions.

Prior to Congress's adoption of the AIA in 2011, §102 of the Patent Act set out certain conditions of patentability. It ensured the novelty of the claimed invention based on its date of invention (§102(a)), and encouraged prompt disclosure of the invention by setting out certain impermissible activities before the patent application is filed (§102(b)). Failure to satisfy the novelty requirement resulted in patent invalidity for anticipation. Failure to satisfy the prompt filing requirement resulted in forfeiture of patent rights, regardless of how novel the invention may have been.[3]

Pre-AIA §102, in pertinent part, reads as follows:

> **§102. Conditions for patentability; novelty and loss of right to patent**

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[3] *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 65 (1998) ("In *Andrews v. Hovey*, 123 U.S. 267, 274 ... (1887), we noted that the purpose of [§102(b)] was 'to fix a period of limitation which should be certain'; it required the inventor to make sure that a patent application was filed 'within two years from the completion of his invention,' *ibid.*"). *See also Application of Foster*, 343 F.2d 980, 987-88 (C.C.P.A. 1965) ("[Section 102(b)] presents a sort of statute of limitations, formerly two years, now one year, within which an inventor, even though he has made a patentable invention, must act on penalty of loss of his right to patent.").

> A person shall be entitled to a patent unless—
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or....

35 U.S.C. §102 (1994). As indicated in its title, the pre-AIA version of §102 imposed two conditions on patentability: "novelty" and "loss of right."

The distinction between novelty (which turned on the date of invention) and loss of right (which turned on the filing date) was well-recognized in the law.[4] Professor Chisum's leading treatise explained as follows:

> The novelty provisions should not be confused with the "statutory bar" or "loss of right" provisions in Section 102.

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[4] Pre-AIA §§102(e) and (g) were also novelty provisions that ensured a patent would only be awarded to the first person to invent an invention. Pre-AIA §102(f) denied the applicant a patent if "he did not himself invent the subject matter sought to be patented."

> Sections 102(b), 102(c)[5] and 102(d)[6] all relate to events and acts by the inventor or by other persons prior to the date when the inventor applies for a patent. The point of a statutory bar is that an inventor of a product or process that may have been new and patentable at the time of invention can lose the right to obtain a patent by tardiness in applying for a patent.

1 Donald S. Chisum, *Chisum on Patents*, §3.02, at 3-9 (2012) ("*Chisum*"). An inventor may have come up with something new, but still lose, be barred from, or forfeit the right to a patent if he or she did not pursue a patent application within the prescribed time. *See, e.g., Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998) ("an inventor loses his right to a patent if he puts his invention into public use before filing a patent application") (citing *Pennock v. Dialogue*, 2 Pet. 1, 24, 7 L.Ed. 327 (1829)). Sections 102(b), (c) and (d) focused on the inventor's actions and/or inaction, not the novelty of the claimed invention. *See also Chisum*, §6.01, at 6-4 ("The general purpose behind all the bars is to require inventors to assert with due diligence

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[5] "A person shall be entitled to a patent unless – (c) he has abandoned the invention." 35 U.S.C. §102(c) (1994).

[6] "A person shall be entitled to a patent unless – (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States." 35 U.S.C. §102(d) (1994).

their right to a patent through the filing and prosecution of a patent application.").

In *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989), this Court explained:

> Sections 102(a) and (b) operate in tandem to exclude from consideration for patent protection knowledge that is already available to the public. They express a congressional determination that the creation of a monopoly in such information would not only serve no socially useful purpose, but would in fact injure the public by removing existing knowledge from public use.

Id. at 148. Sections 102(a) and (b) were part of the 1952 Patent Act's "careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy." *Id.* at 146.

This Court has recognized that pre-AIA §102(b), and the on sale bar in particular, required prompt filing of patent applications. This prevented inventors from commercially exploiting their inventions for longer than the prescribed patent term. In *Pfaff*, the Court stated that "§102 of the Patent Act serves as a limiting provision ... confining the duration of the monopoly to the statutory term." 525 U.S. at 64. Section 102(b) provided the inventor a one-year grace period to determine if the invention was worth the cost of patenting. Thereafter the inventor had to file a

patent application to ensure he or she could not exploit the invention commercially for more than the grace period plus the statutory term. *E.g., General Electric Co. v. U.S.*, 654 F.2d 55, 61 (Ct. Cl. 1981).

B. The AIA's "First Inventor to File" System Replaced Forfeiture as the Incentive for Prompt Filing.

Perhaps the most significant change to U.S. patent law made by the AIA was the replacement of the "first to invent" system with a "first inventor to file" system. H.R. REP. No. 112-98, at 40 (2011). ("The 'America Invents Act' creates a new 'first-inventor-to-file' system."). This change brings U.S. patent law closer to that of every other industrialized nation, each of which uses a first-to-file system. *Id.*

As noted above, one of the policies behind the various statutory bars, including the on-sale bar, was to incentivize the inventor to file diligently a patent application or risk losing the right to a patent. The AIA first-inventor-to-file system expressly replaces this loss-of-right incentive. Congress "provide[d] ample incentive for an inventor to enter the patent system promptly" in the AIA "[b]y adopting the first-to-file system." Cong. Rec. S1371 (March 8, 2011) (1st col.) (remarks of Sen. Kyl).[7] AIA §102(a)(1) preserves the incentive to file promptly by including in the prior art those acts that had resulted in forfeiture under the pre-AIA law. A sale before the prescribed date which makes the claimed invention "available to the public" does not forfeit the patent. It does, however, create a

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[7] All citations to the Congressional Record in this brief are to volume 157 of the daily edition.

disclosure which is given prior art treatment for determining anticipation under §102 or obviousness under §103.

The "available to the public" requirement permits an applicant to make a confidential sale and avoid the on-sale limitation. This possibility, however, reflects a policy decision Congress made to favor disclosure. By preserving the inventor's right to a patent, notwithstanding a confidential sale, Congress chose to provide a continuing incentive for the inventor to make the subject matter of the invention publicly available by filing a timely patent application.

Prompt and complete disclosure of inventions in patent applications is necessary to the bargain between the inventor, who receives exclusive rights in the invention, and the government acting on behalf of the public. The Court recognized in *Bonito Boats*:

> The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years. "[The inventor] may keep his invention secret and reap its fruits indefinitely. In consideration of its disclosure and the consequent benefit to the community, the patent is granted. An exclusive enjoyment is guaranteed him for seventeen years, but upon expiration of that period, the knowledge of the

> invention inures to the people, who are thus enabled without restriction to practice it and profit by its use."

489 U.S. at 150-51 (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186–187 (1933)).

Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co., 153 F.2d 516 (2d Cir. 1946), is the seminal decision on the effect of a secret sale on patent validity under the pre-AIA §102. In that case, the issue was the secret use of a process before the grace period and the sale of the unpatented products of that process. The on-sale bar applied because the patent owner was benefitting simultaneously from both trade secret and patent protection. Judge Hand wrote: "it is a condition upon an inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; ***he must content himself with either secrecy, or legal monopoly.***" *Id.* at 520 (emphasis added).[8]

When enacting the AIA, Congress determined that forfeiting patent rights is more harmful than allowing confidential sales but retaining an incentive to disclose an invention in a promptly filed patent application. Under pre-AIA §102, individual and/or unsophisticated inventors have forfeited their rights to patents because of limited and private uses that did

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[8] In response to comments that the PTO should preserve the rule of *Metallizing Engineering* and related doctrines despite the AIA, the PTO wrote "some of the purposes ascribed to these doctrines in case law appear to be ill-suited to or inconsistent with the AIA." 78 Fed. Reg. 11059, 11075 (3d col.).

not disclose the claimed invention to the public.[9] "The only effect of rulings like these is to create heavy discovery costs in every patent case, and to punish small inventors who are unaware of the pitfalls of the [pre-AIA section 102(b)]." Cong. Rec. S1371 (1st col.) (remarks of Sen. Kyl).[10]

The enactment of the AIA moves the United States closer to the rest of the industrialized world in having a system that awards patents to the first inventor to file an application. Under that standard, there is no reason or need to bar patents after secret commercial use:

> There is no need to also require forfeiture of patents simply because the inventor has made some use of the invention that has not made the invention available to the public. And the current on-sale bar [of pre-AIA §102(b)] imposes penalties not demanded by any legitimate public interest. There is no reason to fear "commercialization" that merely consists of a secret sale or offer for sale but that does not operate to disclose the invention to the public.

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[9] As examples, the Congressional Record cites *Egbert v. Lippman*, 104 U.S. 333 (1881) (corset spring inherently hidden from view and given to only one woman held to be "in public use"); *Beachcombers Int'l, Inc. v. Wildewood Creative Prods., Inc.*, 31 F.3d 1154, 1159-60 (Fed. Cir. 1994) (improved kaleidoscope "in public use" because shown to guests at private party); and, *JumpSport, Inc. v. Jumpking, Inc.*, 191 Fed. Appx. 926 (Fed. Cir. 2006). *See* Cong. Rec. S1371 (1st & 2d col.).

[10] *See also* cases discussed at note 20 *infra*.

Cong. Rec. S1371 (March 8, 2011) (1st col.) (remarks of Sen. Kyl discussing §102 of S. 23). The first-inventor-to-file system provides a strong incentive to file promptly and to disclose the invention to the public. Every day an inventor delays filing a patent application, even if it adds another day's profit from the invention, risks losing twenty years of patent protection to another inventor who files first.

This Court has already determined that "the nature and degree of state [trade secret] protection did not conflict with the federal policies of encouragement of patentable invention and the prompt disclosure of such innovations." *Bonito Boats*, 489 U.S. at 155. The Court recognized that "'[t]rade secret law provides far weaker protection in many respects than the patent law.'" *Id.* (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 489-90 (1974)). The Court elaborated:

> The public at large remained free to discover and exploit the trade secret through reverse engineering of products in the public domain or by independent creation. Thus, the possibility that trade secret protection would divert inventors from the creative effort necessary to satisfy the rigorous demands of patent protection was remote indeed.

Bonito Boats, 489 U.S. at 155 (citing *Kewanee Oil*, 416 U.S. at 490).

C. The Federal Circuit Erroneously Interpreted AIA §102.

Although the words "on sale" are the same in pre-AIA §102(b) and AIA §102(a)(1), the context in which these words appear differs fundamentally. It was error for the Federal Circuit to ignore the entirety of the changes to §102(a)(1) that were enacted by the AIA in adopting the new "first inventor to file" patent system. Courts have a "duty to construe statutes, not isolated provisions." *Graham County Water and Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 290 (2010) (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 568 (1995)). The entirety of the revised §102, particularly in the context of Congress's overall policy decision in enacting the AIA, requires that all forms of prior art be "available to the public."

1. The Plain Language of AIA §102(a)(1) Imposes a Requirement of Public Availability on Prior Art.

AIA §102(a)(1) provides:

> (a) Novelty; Prior Art.—A person shall be entitled to a patent *unless*—
>
> > (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention....

35 U.S.C. §102(a)(1) (2012) (emphasis added). Inventors are entitled to patents "unless" they cannot overcome the prior art, making the identification of prior art fundamental to the patent system.

The AIA struck pre-AIA §102(a) entirely. The following redline reveals the changes made by the AIA to the pre-AIA §102(b):

> (a) Novelty; Prior Art. ~~Conditions for patentability; novelty and loss of right to patent~~ A person shall be entitled to a patent unless—
>
> > (1) the claimed invention was patented, ~~or~~ described in a printed publication, ~~in this or a foreign country~~ or in public use, ~~or~~ on sale, ~~in this country,~~ or otherwise available to the public before the effective filing date of the claimed invention; ~~more than one year prior to the date of the application for patent in the United States~~....

35 U.S.C. §102(a)(1) (2012). Critical differences between the pre- and post-AIA versions include:

> (1) the title is changed to strike "loss of right to patent" and to insert "Prior Art," reflecting the provision's focus on prior art rather than forfeiture;
>
> (2) "claimed" now modifies "invention";
>
> (3) "in this country" no longer appears after "in public use or on sale";
>
> (4) the modifier "or otherwise available to the public" was added following the list of patent-defeating prior art; and,
>
> (5) "more than one year prior to the date of the application for patent in the United States" was changed to "before

> the effective filing date of the claimed invention."[11]

The decision below failed to give full effect to these revisions, despite the express language of §102(a)(1).

The AIA introduces definitions for (1) "claimed invention" as "the subject matter defined by a claim in a patent..." (35 U.S.C. §100(j)) and (2) "effective filing date" of a given claimed invention (35 U.S.C. §100(i)).[12] The subject matter is defined by ***all*** of the claim's limitations. The statute places the "claimed invention" in the prior art only if it was on sale "or otherwise available to the public" before the "effective filing date of the claimed invention." 35 U.S.C. §102(a)(1). The term "otherwise" means "in a different way or manner." *Merriam-Webster's Collegiate Dictionary*, at 823 (10th Ed. 1998). Thus, the "claimed invention" is prior art only *where it is made available to the public, by sale, use, or otherwise.*

By not requiring all of the limitations of the "claimed invention" to be "available to the public," the decision below effectively removed both terms—

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[11] The panel decision below reveals a misunderstanding of the AIA by referring in several places to the patent's "critical date." Pet. App. at 19a, 20a, and 25a-27a. "Critical date" refers to the date more than one year before the filing of a patent application under the 1952 Act to determine the grace period for such filings. *Monon Corp. v. Stoughton Trailers, Inc*., 239 F.3d 1253, 1257 (Fed. Cir. 2001). The relevant term under §102(a)(1), however, is "effective filing date," defined at 35 U.S.C. §100(i) as "the actual filing date of the patent or the application for the patent containing a claim to the invention" or "the filing date of the earliest application for which the patent or application is entitled, as to such invention, to a right of priority...."

[12] *See* note 11 *supra* for the AIA's definition of "effective filing date."

"claimed"[13] and "otherwise"—from the statute. *E.g.*, *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001) ("It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.").

The changes to the title of §102 confirm the imposition of the public availability requirement on all categories of prior art. The words "loss of right to patent" were removed from the title. Only "Novelty; Prior Art" remain. The "public use" and "on sale" provisions of pre-AIA §102(b) were loss of right or forfeiture provisions, not prior art or novelty provisions. The title changes reflect that "in public use" and "on sale" are now categories of prior art.

Under the AIA, Congress created an incentive to file promptly by providing that only the first inventor to file receives a patent. As reflected in its title, AIA §102(a)(1) identifies certain actions and documents as prior art and does not include any loss of right provision. Imposing a public availability requirement on sales is consistent with the fact that qualifying sales are now part of the prior art. Thus, §102(a)(1) should be construed, consistent with its plain language, to require that all the listed forms of prior art must be "available to the public."

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[13] The Federal Circuit decision acknowledges that at least one element of the claimed invention, the dosage, was not disclosed to the public before the effective filing date of the patent. Pet. App. at 24a.

2. Congress Intended to Change the Law Developed under Pre-AIA Court Decisions.

The Federal Circuit relied on pre-AIA law to construe the AIA's §102(a)(1) because it felt Congress's intent to change the law was not sufficiently clear. Appendix to Petition for Certiorari ("Pet. App.") at 11a (citing *Dir., OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 321 (1983)). Congress's intent to impose a public availability standard for prior art is clear from the express statutory language "or otherwise available to the public."

The changes to §102(a)(1) are analogous to the changes to 28 U.S.C. §1367 which the Court considered in *Exxon Mobil Corp. v. Allapattah Servs.*, 545 U.S. 546 (2005). In *Exxon*, the Court addressed whether an amendment to §1367 overruled *Zahn v. Int'l Paper Co.*, 414 U.S. 291 (1973). Responding to an argument that the Court should consider other canons of construction because the amended statute was ambiguous, the Court held: "We can reject this argument at the very outset simply because §1367 is not ambiguous." *Id.* at 567. Earlier in the opinion, the Court stated:

> No sound canon of interpretation requires Congress to speak with extraordinary clarity in order to modify the rules of federal jurisdiction within appropriate constitutional bounds. Ordinary principles of statutory construction apply. In order to determine the scope of supplemental jurisdiction authorized by §1367, then, we must

> examine the statute's text in light of context, structure, and related statutory provisions.

Id. at 558. AIA §102(a)(1) is likewise unambiguous when it requires that prior art must be "available to the public." Congress is no more required to speak with "extraordinary clarity" when amending patent law than it was when amending §1367.

The decision below also erred by construing §102(a)(1) according to pre-AIA case law because, as illustrated in detail above, post-AIA §102(a)(1) includes at least five major changes to pre-AIA §102(b). Congress is presumed to adopt the prior interpretation of a statute only "when it re-enacts a statute without change." *Lorilland v. Pons*, 434 U.S. 575, 580 (1978). Congress fundamentally changed §102 and cannot be presumed to have adopted any prior interpretations.[14]

Section 102 was not reenacted without change. In particular, the subject of the on-sale condition was changed from "the invention" to "the claimed invention." This deliberate change by Congress requires not simply the public availability of the invention but the public disclosure of the invention as claimed, which in this case would have to include the claimed dosage under Helsinn's patent.[15]

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[14] This Court's decision in *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998), continues to govern the first two requirements for an invention to be "on sale," namely, (1) a commercial offer for sale of an invention that is (2) ready for patenting. *Id.* at 67. The public availability requirement was not at issue in *Pfaff*.

[15] The Federal Circuit responded to this issue by citing its 1989 decision that the details of an invention need not be disclosed for

The decision below also relied on *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829), for the proposition that a sale can be invalidating even though it withholds "from 'the public the secrets of [the] invention.'" Pet. App. at 40a. But *Pennock* also does not support this proposition. In *Pennock*, the inventors (Pennock and Sellers) disclosed their invention to a third-party (Jenkins) without imposing any confidentiality obligation, making it publicly available. 27 U.S. at 3. In the language of the Patent Act at the time, the invention was "known or used before the application" and thus a patent was barred. Ch. 11, §1, 1 Stat. 319. The portion of the *Pennock* opinion quoted by the panel is a series of hypothetical statements, introduced by "if," that do not constitute a holding of the case.

3. AIA §102(b) Confirms That Public Uses and Sales Now Create Prior Art, Not Forfeiture Events.

AIA §102(b) provides "exceptions" to the prior art consequences identified in §102(a). Section 102(b) confirms that §102(a) now deals only with the prior art disclosures, and that any loss of right or forfeiture provisions have been eliminated from the statute. Section 102(b) reads:

(b) Exceptions.—

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the on-sale bar to apply. *See RCA Corp. v. Data Gen. Corp.*, 887 F.2d 1056, 1060 (Fed. Cir. 1989). The response is inadequate because it fails to address the law as changed by the new statute. The response is also *dictum* since the *RCA* court found a sufficient technical description of the invention albeit in words different from the claim language. *Id.*

> (1) Disclosures made 1 year or less before the effective filing date of the claimed invention.—A disclosure made 1 year or less before the effective filing date of a claimed invention ***shall not be prior art*** to the claimed invention under subsection (a)(1) if....

35 U.S.C. §102(b) (2012) (emphasis added). The plain language creates an exception to prior art, not an exception to the former loss-of-right provisions.

The legislative history of AIA §102(b) confirms the plain language reading that public availability is required for sales to have any prior art effect. Explaining the one-year grace period of post-AIA §102(b), Senator Leahy (one of the AIA's two namesakes) stated:

> We intend that if an inventor's actions are such as to constitute prior art under subsection 102(a), then those actions ***necessarily*** trigger subsection 102(b)'s protections for the inventor and, what would otherwise have been section 102(a) prior art, would be excluded as prior art by the grace period provided by subsection 102(b).

Cong. Rec. S1496 (March 9, 2011) (2d col.) (emphasis added). Immediately afterwards, Senator Hatch stated:

> The Senator from Vermont is correct. For the purposes of grace-period protection, the legislation intends

> parallelism between the treatment of an inventor's actions under subsection 102(a) that might create prior art and the treatment of those actions that negate any prior-art effect under subsection 102(b).

Id. (3d col.).

Senators Hatch and Leahy's comments were echoed in the House by Representatives Bass and Smith (the other of the AIA's namesakes) as follows:

> Mr. SMITH of Texas. I want to respond to the gentleman from New Hampshire and say that one key issue for clarification is the interplay between actions under section 102(a) and actions under section 102(b). ***We intend for there to be an identity between 102(a) and 102(b). If an inventor's action is such that it triggers one of the bars under 102(a), then it inherently triggers the grace period subsection 102(b).***
>
> Mr. BASS of New Hampshire. I believe that the chairman is correct. ***The legislation intends parallelism between the treatment of an inventor's action under 102(a) and 102(b).*** In this way, small inventors and others will not accidentally stumble into a bar by their pre-filing actions.

Cong. Rec. H4429 (June 22, 2011) (1st col.) (emphasis added). Congress's express intent was for post-AIA §§102(a) and 102(b) to function together as a recitation of prior art and corresponding exceptions. Thus, a non-public sale cannot constitute prior art under AIA §102(a)(1) because a non-public sale is not a disclosure and by definition falls outside the grace period of AIA §102(b).

The word "disclosed" in §102(b)(1)(B) means "publicly disclosed." The plain meaning of the word is clear enough. Congressional intent confirms this:

> I would have thought that the meaning of the word would be clear: a disclosure is something that makes the invention available to the public - the same test applied by section 102(a) to define the scope of the prior art. And "available to the public" means the same thing that "publicly accessible" does in the context of a publication.

Cong. Rec. S1042 (March 1, 2011) (1st col.) (remarks of Sen. Kyl). In short, there is no distinction between "disclosed" in §102(b)(1)(A) and "publicly disclosed" in §102(b)(1)(B). Section 102(b) does not alter the plain language of §102(a) imposing a public availability requirement on any and all forms of prior art in that section.

II. The Legislative History, USPTO Interpretation, and Public Policy Each Provide That "On Sale" Must Make the "Claimed Invention" Publicly Available for Prior Art Treatment.

A. The Legislative History Supports the Public Availability Requirement.

Section 102(a)(1) requires that, to qualify as prior art, the "claimed invention" must be "available to the public." Even if the language of §102(a)(1) were ambiguous, however, the legislative history unambiguously imposes a public availability standard on prior art. The House Report on the AIA explains that "[p]rior art will be measured from the filing date of the application and will typically include all art that ***publicly exists*** prior to the filing date, other than disclosures by the inventor within 1 year of filing." H.R. REP. NO. 112-98, at 42 (2011) (emphasis added). The House Report continues that "the phrase 'available to the public' [was] added to clarify the broad scope of relevant prior art, ***as well as to emphasize the fact that it must be publicly accessible.***" *Id.* at 42-43 (emphasis added). This legislative history confirms the statutory language that all prior art, including sales, must make the invention available to the public. The decision below ignores this Report.

Other portions of the House Report confirm that Congress intended to impose a public availability requirement on prior art, although less explicitly than the portions quoted in the prior paragraph. The report states "[t]he Act ... simplifies how prior art is

determined, provides more certainty, and reduces the cost associated with filing and litigating patents." H.R. REP. NO. 112-98, at 42 (2011). *See also id.* at 40 (the "legislation is designed to establish a more efficient and streamlined patent system that will improve patent quality and limit unnecessary and counterproductive litigation costs."). The AIA §102(a)(1) requirement for claimed inventions to be publicly available to qualify as prior art simplifies how prior art is determined and the decision to seek patent protection because it eliminates the need to scour private records and conduct interviews in search of a disqualifying sale or use. The public availability requirement also lessens discovery in litigation by eliminating an otherwise fact-intensive inquiry into whether the claimed invention was subject to any potentially invalidating uses or sales and whether any such use or sale was experimental.

Proposed versions of §102(a)(1) in draft bills from 2005 through 2008 removed the "public use" and "on sale" terms and included a general "publicly known" clause. This history does not show, however, that by restoring "public use" and "on sale" in the final version Congress intended to retain prior "on sale" law unchanged. Rather, Congress retained public uses and sales as categories of prior art and expressly imposed the requirement that they be publicly available to qualify as prior art.

B. The PTO's Reasonable Interpretation Supports the Public Availability Requirement.

The PTO participated in the AIA legislative process and discussed its implementation with Congress.[16] After the AIA's passage, the PTO conducted an extensive notice and comment procedure to prepare guidance for its personnel on how to administer the statute. 78 Fed. Reg. 11059, at 11060. The PTO concluded that "otherwise available to the public" is a "catch-all" provision that focuses on whether the disclosure was "available to the public" rather than whether it falls within another prior art category defined by the statute. *Id.* at 11075 (2d col.). The PTO agrees that the plain language of §102(a)(1) imposes a public availability requirement on public uses and sales:

> The starting point for construction of a statute is the language of the statute itself.... AIA 35 U.S.C. 102(a)(1) contains the additional residual clause "or otherwise available to the public." Residual clauses such as "or otherwise" or "or other" are generally viewed as modifying the preceding phrase or phrases. Therefore, the Office views the "or otherwise available to the public"

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[16] *See, e.g.*, March 30, 2011 hearing: https://judiciary.house.gov/hearing/hearing-on-h-r-1249-the-america-invents-act-0/ (last visited Aug. 16, 2018); May 16, 2012 hearing: https://judiciary.house.gov/hearing/hearing-on-implementation-of-the-leahy-smith-america-invents-act-0/ (last visited Aug. 16, 2018).

> residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art.

Id. at 11062 (2d col; footnotes omitted).

Under the PTO's guidelines, the public availability requirement applies to all documents and activities itemized in §102(a)(1):

> The Office's interpretation of AIA 35 U.S.C. 102(a)(1) also ensures that the AIA grace period can extend to all of the documents and activities enumerated in AIA 35 U.S.C. 102(a)(1) that would otherwise defeat patentability. In addition, this interpretation avoids the very odd potential result that the applicant who had made his invention accessible to the public for up to a year before filing an application could still obtain a patent, but the inventor who merely used his invention in secret one day before he filed an application could not obtain a patent.[17] Finally, the Office's interpretation is consistent with the interpretation that was clearly expressed by the bicameral sponsors of

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[17] This "very odd potential result" would come about because of the exceptions to prior art in AIA §102(b) discussed above. If §102(a) did not impose a public availability requirement, then a secret use would create prior art which could defeat a patent. AIA §102(b) creates an exception to prior art for disclosures by the inventor up to one year before the filing date. A secret use does not fall within §102(b)'s exceptions, however, because they require disclosure.

> the AIA during the congressional deliberations on the measure.

Id. (footnotes omitted); *see also* Brief for the United States as *Amicus Curiae* at 5, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017), No. 16-1284 ("Brief of USA").

At a minimum, the PTO's interpretation is consistent with the statutory language and legislative history. It also resolves conflicting policies between simplifying the determination of prior art to make the patent system more efficient and objective, providing an incentive to file patent applications promptly, and avoiding exploitation of inventions beyond the statutory term for a patent. Thus, it is eminently reasonable and the Court can rely on it under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), which held:

> We consider that the rulings, interpretations, and opinions of the Administrator under this Act, while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those

> factors which give it power to persuade, if lacking power to control.

Id. at 140.

C. The "Public Availability" Requirement Advances Congress's Policy Objectives

The "public availability" requirement is consistent with Congress's decision to transform the U.S. patent system "from one of non-transparency, subjectivity, unpredictability and excessive complexity, to one that will operate with near-complete transparency, objectiveness, predictability and simplicity...." Robert A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 9 (2012) ("Armitage"). Determining the date of invention under the former "first to invent" system was a fact sensitive endeavor involving determinations of dates of conception and reduction to practice and of the inventor's diligence. *See, e.g., Pfaff*, 525 U.S. at 61 (citing 35 U.S.C. §102(g)). The AIA eliminated fact-sensitive, discovery-intensive, and subjective elements such as the "best mode" defense from pre-AIA §112[18] and "deceptive intention" from pre-AIA §§116, 251, 253, 256, and 288. The AIA also added new §257 on supplemental examination to address the fact-sensitive, discovery-

[18] *Bayer AG v. Schein Pharms., Inc.*, 301 F.3d 1306, 1314 (Fed. Cir. 2002) (whether best mode existed is subjective based on "what the inventor actually believed at the time the application was filed").

intensive, and subjective inequitable conduct defense.[19]

Under pre-AIA §102(b), interested parties cannot readily determine whether a patent will be subject to a public use or on-sale invalidity defense. Prior uses or sales, if any, must be investigated but the relevant evidence may be private. In addition, an inventor must make a judgment as to whether the invention is "ready for patenting" or whether further experimentation is required. *See Pfaff*, 525 U.S. at 64 ("The law has long recognized the distinction between inventions put to experimental use and products sold commercially."). These questions can only be answered after completing extensive document review and multiple interviews or depositions.

The experimental use exception to the on-sale bar is particularly fact sensitive, requiring consideration of the following factors:

> (1) the necessity for public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, . . . (9) the degree of commercial exploitation during testing[,] . . . (10) whether the invention reasonably requires evaluation under actual conditions of

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[19] *See* Armitage, 40 AIPLA Q.J. at 9.

> use, (11) whether testing was systematically performed, (12) whether the inventor continually monitored the invention during testing, and (13) the nature of contacts made with potential customers.

Allen Eng'g, Inc. v. Bartell Indus., Inc., 299 F.3d 1336, 1353 (Fed. Cir. 2002). When the on-sale bar is at issue, the parties naturally will seek documents and testimony bearing on all these factors. In patent prosecution or transactions, this additional due diligence adds cost and risk and, in litigation, the discovery often triggers disputes that require court intervention, extends the length of any trial, and creates a voluminous record for appeal.

The Federal Circuit's failure to recognize that the public availability requirement applies to claimed inventions undermines a critical purpose of the AIA: to make the patent system simpler and more predictable. By reducing the effort to achieve due diligence or discovery to determine if a sale is prior art under §102(a)(1), Congress created the certainty required for parties investing in patent applications, pursuing licenses or acquisitions, and evaluating patent litigation. In addressing its concern for costs and wasted resources, Congress balanced the need for limiting exclusive rights in a free market against the importance of the patent system to U.S. innovation. The Federal Circuit decision interferes with this policy balance uniquely committed to the legislature, not to the judiciary.

The Federal Circuit decision also interferes with Congress's attempt to reduce the number of fact

issues that dominated pre-AIA case law. The Federal Circuit's opinion states: (1) "the AIA did not change the statutory meaning of 'on sale' ***in the circumstances involved here***," Pet. App. at 20a (emphasis added); and (2) "[w]e do not find that distribution agreements will always be invalidating under §102(b) [*sic* – 102(a)]. We simply find that this particular Supply and Purchase Agreement is." Pet. App. at 43a. The opinion concurring in the denial of rehearing *en banc* also portrayed the decision as fact-specific. Pet. App. at 5a. Thus, the decision below will continue to require substantial time and expense for investigation, discovery, motion practice, trial, and appeal to define the specific sales arrangements that do or do not constitute prior art. This result is contrary to the Congressional intent "to reduce the costs associated with filing and litigating patents." H.R. REP. NO. 112-98, at 42.

Moreover, old "public use" and "on sale" law led to many outcomes that defied logic and no longer serve any policy objective under the AIA.[20] As one commentator wrote:

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[20] *See, e.g., Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357-1358 (Fed. Cir. 2001) (refusing to recognize a "supplier" exception to the on-sale bar); *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998) (finding an inventor's own secret commercial use before the grace period may be a public use barring patentability); *Evans Cooling Systems, Inc. v. General Motors Corp.*, 125 F.3d 1448, 1454 (Fed. Cir. 1997) (refusing to create an exception to the on-sale bar for sales before the grace period that result from a misappropriation of the invention by a third party); *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946) (applying the on-sale bar to sales before the grace period of unpatented products made by the secret use of the patented

> It is one of the ironies of the pre-AIA patent law that §102(a)'s invalidating "use" must make an invention accessible to the public, while §102(b)'s "public use" can include private uses that are not accessible to the public. *See Woodland Trust*, 148 F.3d at 1370; *Trading Tech. Int'l, Inc. v. eSpeed, Inc.*, 507 F. Supp. 2d 883, 893 (N.D. Ill. 2007), *aff'd*, 595 F.3d 1340 (Fed. Cir. 2010) (finding that the secret commercial use of an inventor's own invention may constitute public use).

Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 450 n.97 (2012). If the Court retains the pre-AIA construction of "on sale," it will extend the uncertainty and oddity of the old interpretation. Further, it will undermine Congress's objectives to make the outcome of patent prosecution and litigation more predictable and efficient.

In addition to making the patent system more efficient, objective, and predictable, other policy considerations support excluding secret sales from the prior art under §102(a)(1). Congress also imposed this public availability requirement on prior art to protect U.S. businesses from having their inventions

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process); *Hall v. Macneale*, 107 U.S. 90, 96 (1883) (finding the sale of "burglar-proof" safes to be a public use despite testimony that technology was completely concealed within the safe).

stolen or patents invalidated by unscrupulous foreign competitors. Senator Kyl stated:

> Finally, ***validating prior art will depend on publicly accessible information***, not private activities that take place, for example, in a foreign land. As a result, it will be impossible for a third party who derived the invention from a U.S. inventor's public disclosure or patent application to steal the invention or sabotage the U.S. inventor's patent.

Cong. Rec. S5320 (Sept. 6, 2011) (3d col.) (emphasis added). To allow secret sales anywhere in the world to serve as prior art would facilitate the theft of U.S. inventions, contrary to Congress's expressed intent. Congress intended to protect U.S. inventors from this risk by confirming that a sale before the effective filing date must make the "claimed invention" "available to the public" to qualify as invalidating prior art.

Congress also removed secret sales as a forfeiture of patent rights to achieve greater substantive harmonization of patent laws among the U.S., Europe, Japan, and other countries. AIPLA is not aware of any foreign country that uses a first-to-file system and also includes secret sales as a basis for a loss of right to a patent.[21] The House Report on the

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[21] The Government made a similar assertion in its amicus brief below. Brief of USA at 10. The fact no other country considers secret sales to be prior art confirms that the adoption of a first-inventor-to-file system provides a sufficient policy incentive to ensure early disclosure. It also mitigates any concern that

AIA cites "the value of harmonizing our system for granting patents with the best parts of other major patent systems throughout the industrialized world for the benefit of U.S. patent holders" as one of the motivations for the bill. H.R. REP. NO. 112-98, at 39. Conversely, maintaining secret sales as a basis for losing the right to a patent would detract from Congress's goal of further harmonizing U.S. patent law with that of other major industrialized nations.

III. CONCLUSION

The Court should reverse the decision below and uphold the AIA's express requirement that sales of the "claimed invention" must be "available to the public" to qualify as prior art.

Respectfully submitted,

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companies may keep their process inventions secret for years and then file patent applications at the last minute.

No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., ET AL.,

Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF OF THE ASSOCIATION FOR ACCESSIBLE MEDICINES AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

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INTEREST OF *AMICUS CURIAE*[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing the interests of the generic and biosimilar medicines industry. AAM represents manufacturers and distributors of finished generic and biosimilar pharmaceuticals, manufacturers and distributors of bulk active pharmaceutical ingredients, and suppliers of other goods and services to the generic and biosimilar pharmaceutical industry. Its members provide Americans with generic and biosimilar medicines that are as safe and effective as their brand-name counterparts, but are substantially more affordable. In 2017, generic medicines accounted for roughly 90% of all prescriptions dispensed in the United States but only 23% of total spending. Generic medicines saved patients, taxpayers, and health care payers over $265 billion in 2017 compared to their brand-name counterparts.

AAM seeks to provide courts with the perspective of the generic and biosimilar pharmaceutical industry on important legal issues impacting its members, and to highlight the potential industry-wide consequences of significant pending cases.

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[1] Pursuant to this Court's Rule 37.3(a), counsel for all parties consented to the filing of this brief. Pursuant to this Court's Rule 37.6, *amicus* states that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amicus*, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of this brief.

AAM's members are frequently involved in pharmaceutical patent litigation in which they rely on invalidity defenses such as the on-sale bar. Invalid patents undermine the legitimacy of the patent system, stifle competition, and impede consumers' access to low-cost medicines. AAM members have a significant interest in ensuring that statutory limits to the patent monopoly are enforced according to their terms.

Helsinn and its *amici*'s strained interpretation of the text of § 102(a)(1)—under which the on-sale bar now extends only to sales that are in some way "available to the public" or, as suggested by the United States, made to "an ultimate consumer"—threatens to destabilize the competitive equilibrium contemplated by Congress. Their novel approach, which has no support in the text of the statute, could insert rampant gamesmanship and uncertainty into the national pharmaceutical market. The members of AAM therefore have a strong interest in the outcome of this case.

SUMMARY OF ARGUMENT

For nearly two hundred years, the on-sale bar has funneled inventors into the patent system by preventing inventors from commercializing their inventions indefinitely before filing a patent application. By encouraging inventors to file for patents, the on-sale bar promotes disclosure and the "Progress of Science and useful Arts." U.S. Const. art. 1, § 8, cl. 8. At the same time, the rule enforces the constitutional limit that patents be granted for "limited Times." *Id.* Both of these virtues are well-served by the long-settled principle that secret sales—that do not disclose the details of an invention subject to the sale—nevertheless

place the invention "on sale" and thus trigger the statutory clock. *Woodland Tr. v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

Helsinn argues that Congress reversed course in the America Invents Act ("AIA") and lifted the on-sale bar for any sale in which at least one "term" of the sale is not disclosed to the public. Teva has already ably explained why Helsinn's interpretation is foreclosed by the plain text of the on-sale bar and the history of the provision. AAM writes to emphasize the extent to which Helsinn's interpretation (and the government's variant) would invite manipulation and foster confusion in the pharmaceutical market, with deleterious consequences for patients, taxpayers, and others who seek more affordable medicines.

It takes little imagination to see how Helsinn's rule would allow a drug manufacturer to extend the effective life of its monopoly. A manufacturer simply could market the drug through a partially confidential transaction and thereby obtain the benefits of commercialization without starting the clock on its patent rights. Rather than having to choose between commercialization and secrecy, an inventor under Helsinn's rule could have both. That rule would be detrimental in every sector of the economy, but it is particularly pernicious in the context of pharmaceuticals where it prevents the public from obtaining generic medicines long after the patent term should have expired.

The government's proposed variant in which only sales to ultimate customers trigger the bar is equally manipulable. Indeed, in the context of pharmaceuticals,

the government's rule would in almost every case afford a manufacturer the ability to delay seeking a patent because drug manufacturers almost never sell directly to consumers.

Even where Helsinn's rule and the government's variant do not lead to intentional manipulation, they will cloud patent rights by generating significant doubt as to whether sales are or are not invalidating. A generic manufacturer may not always be able to ascertain whether a particular sale is sufficiently confidential to avoid the on-sale bar. This uncertainty would be particularly harmful in the pharmaceutical industry, where both brand-name and generic manufacturers will not make investments unless patent rights are clear.

Helsinn suggests that the time needed to seek FDA approval justifies delaying the patenting requirement. But Congress already took account of that delay when it enacted the patent term extension statute, 35 U.S.C. § 156, which confers an additional period of exclusivity for the time spent awaiting FDA approval. Helsinn's position would allow inventors to "double dip" by commercializing their product while awaiting FDA approval while *also* benefiting from the patent term extension.

Opening patent law to a manipulable rule that engenders uncertainty risks underming a competitive market carefully calibrated by Congress for the past four decades. The on-sale bar's application to sales that are not fully public preserves the public's interest in a market where robust competition ensures better patient outcomes and greater access to life saving medicines. Every year the public is delayed in obtaining generic

medicines means higher pharmaceutical prices and worse patient outcomes. The Court should affirm the Federal Circuit;s interpretation of the on-sale bar and its judgment that Helsinn's '219 patent is invalid because Helsinn placed its invention on sale more than a year before it applied for the patent.

ARGUMENT

AAM agrees with Teva that the on-sale bar means what it has always meant: an item is "on sale" if it is sold or offered for sale from one entity to another, even if details of that sale are confidential. Helsinn does not contest that, despite having ample opportunity to do so, Congress has not tinkered with the text of the on-sale bar itself. Instead, Helsinn and its *amici* ask this Court to jettison nearly two centuries of precedent based on an unassuming residual clause added to the end of § 102(a)(1) by the AIA. But this Court has long held that "modification by implication" of a statute with a "settled construction" is "not favored." *United States v. Madigan*, 300 U.S. 500, 506 (1937). If Congress "intend[ed] to effect a change of that kind," it would have "provide[d] a relatively clear indication of its intent in the text of the amended provision." *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1520 (2017).

What makes Helsinn's construction of the on-sale bar all the more dubious is that it would frustrate core policies of patent law and their application to the pharmaceutical industry in particular. In enacting both the Patent Act and the Hatch-Waxman Act, Congress struck a delicate balance between innovation on the one hand, and public access to life-enhancing and life-saving

inventions on the other. By allowing commercialization through confidential sales, Helsinn would disrupt this careful balance. Brand-name pharmaceutical companies would have free license to manipulate their commercial activity to extend the duration of their government-sanctioned monopoly (and the profits that go along with it) far beyond that which Congress ever inteded. In the process, these companies would deprive patients of sorely needed low-cost drugs, thereby frustrating one of the main goals of the Hatch-Waxman Act.

By asking this Court to effect a seismic shift in the law from a small change to § 102(a)(1), Helsinn asks the Court to find the proverbial elephant hidden in a mousehole. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). But that is not how statutory construction works. The Court should affirm the Federal Circuit's holding that Helsinn's patent is invalid because Helsinn placed it on sale more than a year prior to filing.

I. Generic And Biosimilar Drug Companies Serve a Critical Role in the Pharmaceutical Marketplace by Providing Affordable Access to Medicines.

Manufacturers of generic drugs have long ensured affordable access to medicines for millions of American consumers. Taxpayers, employers, insurance companies, and state and federal governments have benefited from trillions of dollars in savings from lower-cost alternatives to brand-name medicines.

The United States is a global leader in generic drug use.[2] In 2016, generic drug companies filled 89% of Americans' prescriptions and manufactured over 61 billion prescription doses in the United States.[3] The affordability of generic drugs has led to expanded access to medications that has improved patient outcomes. Experts estimate that half of patients with chronic diseases do not take their medications as prescribed, and non-adherence to prescription drugs accounts for approximately 125,000 deaths annually.[4] Patient abandonment rates for generic medicines, however, are approximately 66% lower than for branded drugs, an unsurprising figure given that 90% of all generic medicines are available to consumers for less than $20.[5]

Not only is the generic marketplace good for patients, but it benefits taxpayers, too. Although brand-

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[2] Olivier J. Wouters, Panos G. Kanavos, & Martin K. Mckee, *Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending*, 95 Milbank Q. 554, 564 (2017), https://www.milbank.org/wp-content/uploads/2018/01/WOUTERS_et_al-2017-The_Milbank_Quarterly.pdf.

[3] Ass'n for Accessible Medicines, White Paper, *Ensuring the Future of Accessible Medicines in the U.S.*, at 4 (2018), http://accessiblemeds.org/sites/default/files/2018-02/AAM-Whitepaper-Ensuring-Future-of-Generic-Medicines.pdf [hereinafter *Ensuring the Future*]; Ass'n for Accessible Medicines, *Generic Drug Access & Savings in the U.S.*, at 7 (2017), http://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf [hereinafter *Savings*].

[4] *Ensuring the Future*, *supra* note 3 at 5.

[5] *Id.*

name drugs account for only 11% of prescriptions dispensed in the U.S., they account for more than 74% of total drug spending. One of the largest subsidizers of prescriptions is the federal government.[6] In 2015, the U.S. government paid roughly 43% of all retail prescription drug costs—29% through Medicare and 10% through Medicaid.[7] Medicare and Medicaid saved $77 billion and $37.9 billion, respectively, in 2016 due to savings associated with lower-cost, generic drug options.[8] This equates to an average annual savings of $1,883 per Medicare enrollee and $512 per Medicaid enrollee.[9] With health expenditures climbing 5.8% in 2015 and accounting for 17.8% of Gross Domestic Product, the savings associated with generic drug options has become an indispensable component of national health policy.[10]

Since the mid-eighties, Congress has prioritized competition in America's prescription drug policy by enacting legislation designed to protect the entry of generic drugs onto the market. One of the primary goals of the Drug Price Competition and Patent Term

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[6] *Savings*, *supra* note 3 at 33.

[7] Peter Olson & Louise Sheiner, *The Hutchins Center Explains: Prescription Drug Spending*, Brookings Inst. (Apr. 26, 2017), https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/.

[8] *Ensuring the Future*, *supra* note 3 at 6.

[9] *Id.*

[10] *Savings*, *supra* note 3 at 8.

Restoration Act, commonly known as the Hatch-Waxman Act, was to facilitate the entry of generic drugs. The Hatch-Waxman Act not only streamlines the FDA approval process for generic drug applications, but also incentivizes challenges to the validity of brand-name patents by offering a 180-day exclusivity period to generic companies who successfully obtain a court ruling that the brand patent at issue is valid or not infringed.[11]

Congress's foray into prescription drug policy, however, has not deterred anti-competitive practices by brand drug manufacturers. Such manufacturers may engage in a variety of practices known as "evergreening" that seek to extend a drug's period of exclusivity as a means of preventing low-cost alternatives from entering the market. For instance, they may attempt to "patent 'new inventions' that are really just slight modifications of old drugs."[12] Such patents result in fresh 20-year monopolies on drugs that should be in the public domain. Alternatively, manufacturers may take advantage of a provision of the Hatch-Waxman Act staying generic entry for 30 months under certain circumstances, by securing seriatim stays that can delay generic entry indefinitely.[13] Those

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[11] 21 U.S.C. § 355(j)(5)(B)(iv).

[12] Roger Collier, *Drug Patents: The Evergreening Problem*, 185 Can. Med. Ass'n J. E385, E385 (2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3680578/; *see generally* Scott C. Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. Health Econ. 327 (2011).

[13] Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 Tex. L. Rev. 685, 711-15 (2009) (explaining this strategy in detail).

practices inhibit innovation and harm the nation's fiscal health.

In this case, Helsinn's position reflects a variation on the evergreening theme: it seeks to obtain monopoly profits for a period exceeding the statutorily prescribed monopoly period. Helsinn's position is inconsistent with the national policy of allowing generic entry after that period has expired to ensure affordable access to drugs.

II. The On-Sale Bar Promotes Disclosure of Inventions by Limiting the Time in Which Inventors Must Seek Patent Protection After They Have Commercialized Their Inventions.

The on-sale bar ensures that patentees can obtain monopoly profits for the statutorily prescribed period—and no longer. This Court has recognized that policy underlying the on-sale bar for nearly two centuries. Treating a secret sale not as a "sale" for purposes of the on-sale bar would violate the on-sale bar's text and frustrate the bar's historic purpose.

A. The On-Sale Bar Has Applied to Confidential Sales for Nearly 200 Years.

This Court recognized nearly 200 years ago that confidential sales invalidate patents in *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 23-24 (1829). In *Pennock*, the Court invalidated the plaintiff's process patent on the grounds that he had made and sold the output of that process (fire hoses) seven years prior to filing his patent application. *Id.* at 9. Although Pennock never disclosed the details of his inventive process, the Court nonetheless held that Pennock forfeited his right to a

patent by engaging in pre-grant sales of the article produced by that process. *Id.* at 23-24.

Justice Story rooted the Court's holding in the constitutional limit that patent monopolies be granted for "limited times." *Id.* at 16. Recognizing the potential for patent owners to extend their lucrative monopolies through such early sales activities, the Court reasoned:

> [i]f an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention[]...and make, and sell his invention publicly, and thus gather the whole profits of it[]...and then only, when the danger of competition should force him to procure the exclusive right, he should be allowed to take out a patent, and thus exclude the public from any further use...*it would materially retard the progress of science...and give a premium to those who should be least prompt to communicate their discoveries.*

Id. at 19 (emphasis added).

Congress formally incorporated a prohibition on patenting "on sale" inventions into the Patent Act in 1836. Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119. Although the Patent Act has undergone substantial revisions since 1836, this statutory "on sale" language has survived unchanged. And as recently as 1998, this Court reaffirmed *Pennock*'s holding. *Pfaff v. Wells Elecs. Inc.*, 525 U.S. 55, 64 (1998).

B. The Policies Justifying the On-sale Bar Are Served by Treating Confidential Sales as Sales.

In the wake of *Pennock* and the statutory codification of the on-sale bar, courts have identified two primary policies served by this rule. First, the bar "encourages an inventor to enter the patent system promptly." *Woodland Trust*, 148 F.3d at 1370. Second, and relatedly, the bar serves to "prohibit[] the commercial exploitation of [a protected invention] beyond the statutorily prescribed time period." *Cont'l Plastic Containers v. Owens Brockway Plastic Prods., Inc.*, 141 F.3d 1073, 1079 (Fed. Cir. 1998).

Using these policies as guideposts, courts have repeatedly endorsed the rule that commercial sales trigger the one-year period to apply for a patent even though some of the details of the sale or the invention may not be public. *See, e.g., Woodland Tr.*, 148 F.3d at 1370 ("Thus an inventor's own prior commercial use, albeit kept secret, may constitute a...sale under § 102(b), barring him from obtaining a patent"); *accord Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001).

The secret sale bar acknowledges that boundless pre-grant commercial activity undermines the constitutional rule that patent monopolies be granted for "limited Times." U.S. Const. art. I, § 8, cl. 8. So long as an inventor can profit from an invention by keeping it secret—without any repercussions with respect to the patentability of that invention—there is little incentive for that inventor to seek out a congressionally mandated term limit to commercial exclusivity. This "premium to

those who should be least prompt to communicate their discoveries" is precisely the objective that the on-sale bar is designed to neutralize. *Pennock*, 27 U.S. at 19.

Moreover, tacking on a government sanctioned monopoly *after* a limitless period of commercial profits presents a problem of constitutional dimension. If a patent owner can effectively extend its exclusivity indefinitely through confidential sales prior to a twenty-year patent term, the patent grant will effectively morph into an infinite monopoly right to those savvy market participants who are able to keep an invention under their confidential control. In the complex commercial marketplace of the 21st century, the virtues of the confidential sales rule continue to apply with equal if not more compelling force.

C. The Policies Underlying the On-Sale Bar Are Consistent with Treating Sales to Distributors as Sales "to the Public."

Of course, the Court cannot resolve this case based on policy alone: the text of the on-sale bar provision is paramount. But the policies underlying the on-sale bar powerfully support Teva's textual argument that Congress did not change the meaning of "on sale" by the oblique mechanism of adding an *additional* category of prior art. Likewise, even if Helsinn and the government are correct that the on-sale bar applies only to "public" sales, the policies underlying the on-sale bar would still inform the interpretation of the word "public." In view of those policies, the Court should hold that any sales that "take place between two separate entities" are sufficient to trigger the on-sale bar. *Special Devices*,

Inc., 270 F.3d at 1356 (internal quotation marks omitted).

Classifying "secret" sales as sales for purposes of the on-sale bar comports with the principle that the Patent Act should be construed in accordance with common-law commercial principles. In *Impression Products, Inc. v. Lexmark International, Inc.* 137 S. Ct. 1523 (2017), this Court held that the "common law's refusal to permit restraints on the alienation of chattels" is incorporated into the Patent Act via the exhaustion doctrine, observing that "[w]here a common-law principle is well established, ... courts may take it as given that Congress has legislated with an expectation that the principle will apply except when a statutory purpose to the contrary is evident." *Id.* at 1536 (quotation marks omitted; alterations in original). Consistent with that principle, the Federal Circuit has held that in determining the question of whether an offer for a sale exists, the question must be "'analyzed under the law of contracts as generally understood'" and "must focus on those activities that would be understood to be commercial sales and offers for sale 'in the commercial community.'" *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363, 1373 (Fed. Cir. 2016) (en banc) (citations omitted).

These principles require classifying Helsinn's sale as a "sale" for purposes of the on-sale bar. There is no doubt that Helsinn made a "commercial offer for sale," *Pfaff*, 525 U.S. at 67. Whether the sale was secret or not does not affect whether a sale occurred. By contrast, Helsinn's rule—that a product is not "on sale" unless all aspects of the underlying invention have been publicly disclosed—and the government's rule—that a product is

not "on sale" unless it is on sale *at retail*—have no basis in any commercial principles.

While Helsinn does not clearly recite how its test distinguishes "secret" from public sales, it appears to support a rule in which a sale is not "public" unless all details of the sale are publicized. Such a test is untethered from the on-sale bar's purposes. The purposes of the on-sale bar are to encourage early entry into the patent system and to prevent patent owners from undermining constitutional and statutory term limits—by limiting the benefits associated with commercial activity prior to patenting. Both of these goals are threatened by even a single sale where profit flows from one entity to another, and, therefore, it follows that the on-sale bar rule should apply equally to these transactions. As demonstrated by the sale at issue in this case, a single sale to a single buyer can reward the patent owner with profits to the tune of millions of dollars. Whether these millions are made from a single buyer or a broader group does not matter to the incentive structure contemplated by on-sale bar policies. Rather, it is the exchange of consideration—not the identity of the purchaser—that benefits the patent owner.

The government's proposed rule, that a sale is not to the "public" unless it is to the "ultimate consumer," is equally unmoored to the purpose of the on-sale bar and impractical and confusing to boot. The on-sale bar principle is tied to the incentive structure created by an exchange of benefits—not the identity of the sale partner. Moreover, determining an "ultimate consumer" is fraught with unnecessary difficulties and

creates space for difficult line drawing. Corporate supply chains often rely on wholesalers, distributors, and retailers for their profits. The on-sale bar should not turn on how companies structure their vertical supply relationships.

III. A Narrow On-Sale Bar as Proposed by Helsinn Would Promote Manipulation in the Commercial Drug Market and Disrupt Congress's Carefully Balanced Scheme.

Helsinn and its *amici* contend that the AIA dramatically narrowed the on-sale bar. While Helsinn does not offer a clear articulation of what it means for a sale to be "public," it appears to suggest that a sale is not "public" unless not only the sale itself, but also the details of the invention, are publicly disclosed.[14] This rule would allow patent owners to manipulate the system to reap a windfall from both pre-grant and post-grant exclusivity profits. Moreover, the rule would fundamentally alter the pharmaceutical landscape by extending brand-name drug companies' ability to control the market for life-altering drugs.

A. Under Helsinn's Position, Patent Owners Will Enjoy a Double Benefit During FDA Proceedings.

Helsinn's proposed rule would permit an improper form of "double dipping" by patent owners. Federal

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[14] The United States goes even further, arguing that an invention is "on sale" within the meaning of Section 102(a)(1) only when a product embodying the invention can be purchased by its "expected ultimate customer."

patent law compensates patent owners for the period spent waiting for FDA approval by giving them a patent term extension of up to five years. Under Helsinn's position, however, patent owners could *both* obtain monopoly profits during the period spent waiting for FDA approval *and* obtain the five-year term extension, in contravention of Congress's carefully balanced scheme.

In the Hatch-Waxman Act, Congress enacted a "patent term extension" ("PTE") provision designed to compensate patent owners for certain delays in commercialization due to FDA regulatory proceedings. *See* 35 U.S.C. § 156. The Hatch-Waxman Act contemplates that inventors might obtain patents while FDA proceedings are pending, and therefore effectively lose a portion of their statutory monopoly period. To compensate for the time associated with FDA proceedings, Section 156 provides opportunities for patent owners to extend the term of a patent for up to five years, subject to certain limitations. In order to be eligible for a term extension, the patent holder must apply for PTE within a limited period of time following regulatory approval. Critically, although drug manufacturers routinely obtain multiple patents on the same product, the PTE statute states that "in no event shall more than one patent" be extended for any particular product. 35 U.S.C. § 156(e)(1).

Helsinn's position would allow patent owners to obtain the functional equivalent of patent term extensions for multiple patents that exceed the five-year maximum prescribed by § 156. According to Helsinn, inventors can now engage in limitless pre-grant

commercial sales during the FDA approval process (so long as they keep some measure of their invention secret from the public and/or "ultimate customer"). Thus, if Helsinn prevails, a drug company could commercially market a patented product and therefore exercise a functional monopoly while FDA proceedings are pending, without filing a patent application. Then, 364 days after the FDA approves the product and it goes on sale to the general public, the company could file *multiple* patent applications—thus achieving the functional equivalent of a patent term extension on all of those patents.

Further, the length of that functional patent term extension may well exceed five years. The average time from FDA application to approval of drugs is 12 years.[15] Thus, an inventor may begin commercializing a patent a decade or more before FDA approval. If the inventor waits until 364 days after FDA approval to file the patent application, the inventor would achieve the equivalent of a decade-long patent term extension for multiple patents—in contravention of Congress's considered decision to limit the term of the extension to five years for one patent.

Congress has considered the harm associated with regulatory delay and resolved that issue by compensating patent owners with PTE. Piling on the benefit of pre-grant commercial activity would

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[15] Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs*, JACC: Basic to Translational Science (Apr. 2016), http://basictranslational.onlinejacc.org/content/1/3/170.

constitute a double benefit that undermines the careful balance achieved by § 156.

B. Helsinn's Rule Would Open the Door to Manipulation by Patent Owners and Yield Particularly Pernicious Consequences for Drug Consumers.

Helsinn's proposed rule would allow brand pharmaceutical companies to obtain monopoly profits for a period far exceeding the statutorily-prescribed period—a result irreconcilable with the purpose of the on-sale bar.

Helsinn contends that a sale is not a "sale" for purposes of the on-sale bar if conducted in secret. If Helsinn's position prevails, patent owners will obtain a windfall: patent owners could tack the profits earned from these secret sales onto a twenty-year term of patent exclusivity. Such a position would effectively extend the patentee's statutory period of monopoly. During the period of secret sales, the inventor would have an effective monopoly on the commercialization of the invention because the invention is by definition novel, and others could not exploit it while it is kept secret. Then, during the patent exclusivity period, the patentee would enjoy a statutory monopoly. That result is irreconcilable with Congress's goal of ensuring that inventors may exercise monopoly rights during the statutorily prescribed period—and no more.

Moreover, Helsinn appears to propose a rule in which patent owners could publicly announce sales without triggering the on-sale bar, so long as they do not reveal the details of the invention themselves. Indeed, under

Helsinn's apparent rule, even if an inventor publicizes *some* details of the invention, it can avoid the on-sale bar merely by not publicizing *every* detail. This case illustrates the point: Helsinn publicized to the world that its agreement with distributor MGI for "palonosetron" was ushering the company into the "$1 billion North American market for 5-HT, antagonists." J.A. at 251-52. The only relevant language redacted from Helsinn's public filings was a description which disclosed the 0.25 mg dosage of the drug, yet Helsinn now contends this redaction allows it to evade the on-sale bar.

By making such announcements, inventors attract follow-on investment and chill competition. Here, for example, Helsinn's announcements put generic firms on notice that another patent may be issuing in the field of 5-HT antagonists, thus deterring those firms from developing such pharmaceuticals. Helsinn was therefore able to profit from its invention as if it possessed monopoly power. By delaying the filing of its patent application until over a year after the announcement, Helsinn improperly extended its monopoly period.

If the Court adopts Helsinn's proposed rule, patent owners will inevitably exploit it. Although the sale between Helsinn and MGI was a single buyer transaction, the narrow on-sale rule proposed by Helsinn places no bounds on the number or volume of transactions that trigger the on-sale bar—only the terms of its secrecy. Sales could conceivably extend to dozens of firms. So long as participants adhere to some measures of confidentiality, patent owners will be in a position to reap substantial benefits.

Not only will extending patent monopolies increase costs during the years of the patentee's improperly-extended monopoly, but it will create the risk of freezing generic drug manufacturers out of the market entirely. The longer the patent term, the more likely that an eventual generic or biosimilar drug will be outdated by the time the patent expires. Longer patent terms can harm patients and our health care system by keeping drug prices high for longer and making it more difficult for competitors to earn a return on investment on drugs that have been superseded. Thus, rigorous adherence to the statutory patent term requirement is necessary to ensure that hospitals and patients can buy generic drugs that are nonetheless state-of-the-art.

Helsinn's proposed rule would also create the risk of a different type of manipulation: the filing and assertion of a new species of "submarine" patents. Submarine patents, or patents that "submerge" during a lengthy prosecution process and then surface after the grant, historically presented a significant disruption to innovators who invested in products with an unknown patent thicket looming in ex parte prosecution proceedings. *See generally Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378 (Fed. Cir. 2005), *amended on reh'g*, 429 F.3d 1051 (Fed. Cir. 2005). The AIA's first-to-file regime, coupled with the modern rule that the statutory period commences as of the date of the patent application (rather than the date the patent is granted), were intended to solve this notorious problem. But abandoning the secret sale rule would reintroduce the same problem in a different form: inventors of

concealable inventions could commercialize their inventions for years or decades before surfacing and filing for patents. Industry participants who independently conceive of the same invention will have relied on the absence of a patent in that market to justify their investment, only to be surprised with infringement claims years later. As Professor Lemley explains:

> Inventors of easily concealable inventions like manufacturing processes could keep their process inventions secret for years or even decades and then surface and file a patent application. Because that application was filed later, the patent would expire later. It could take an existing industry by surprise because others who developed but did not patent the technology would not be able to use their own secret use as prior art to defeat the patent. And while some inventors will not want to take the risk that someone else patents the idea before them, the AIA actually lessens that risk by giving the first inventor a prior user right. [Requiring prompt applications after commercialization] would encourage delay in patenting in the hopes of extending the life of a patent. That is directly contrary to the goals of first inventor to file in the AIA, which encourages early filing of patent applications.

Mark A. Lemley, *Does "Public Use" Mean the Same Thing It Did Last Year?*, 93 Tex. L. Rev. 1119, 1132 (2015) (footnotes omitted).

Helsinn maintains that the AIA's shift from a first-to-invent to a first-to-file regime resolves concerns about manipulation. According to Helsinn, an inventor who delays the filing of an application risks losing the patent to another inventor who files first, so there is no risk that an inventor will deliberately delay in filing a patent application. Helsinn's contention ignores the reality of how the pharmaceutical industry actually operates. First, although the AIA enacted a first-to-file regime, it did not eliminate the bedrock rule that only the *inventor* is entitled to a patent. Indeed, it expressly provides that a disclosure in a patent application "shall not be prior art to a claimed invention" if "the subject matter disclosed was obtained directly or indirectly from the inventor or a joint inventor." 35 U.S.C. § 102(b)(2)(A). And it creates a new procedure known as a "derivation proceeding," which allows a later-filing applicant to obtain a patent by proving that the earlier-filing applicant "derived" the invention from the later-filing applicant. 35 U.S.C. § 135. Thus, so long as an inventor reasonably believes that another person will not independently conceive of the same invention, the inventor can engage in "evergreening" tactics without a risk of losing the right to file an application later.

In the real world, brand-name drug companies can engage in such manipulative tactics without running the risk of losing the right to a patent. As previously noted, a common "evergreening" tactic is to extend a patent on an existing drug by patenting a new means of storage or administration, a slight modification, a new release mechanism, or the like. The "inventors" of such "inventions" will almost invariably be the patentees of

the existing drug: they are the sole entities in a position to conduct the research necessary for these follow-on inventions, given their monopoly over production and distribution of the drug during the statutory period. Blocking patents may restrict researchers' abilities to develop certain drugs, and other researchers may lack the necessary resources for drug development. Patent owners can engage in those manipulative tactics that extend the statutory period regardless of whether there is a first-to-invent or first-to-file regime.

IV. Upending Traditional On-Sale Principles Will Infuse Uncertainty into the Commercial Marketplace for Both Brand-Name and Generic Drug Manufacturers.

Reversing hundreds of years of case law would have profound implications for upsetting consumer norms and corporate business practices. Helsinn's exceedingly thin conception of the on-sale bar—that sales not only need to be public, but need to expose the details of the patented invention in order to constitute prior sale under Section 102(a)(1)—also opens the door to the reinterpretation of other key patent limits grafted from the 1952 Act into the AIA.

Helsinn does not explain what degree of secrecy is required to shield sales from its proposed new rule. Confidentiality agreements come in many forms and, as shown by Helsinn's agreement with MGI, some agreements leave very little information confidential to the transacting parties. Would only certain claim elements need to remain secret to avoid the on-sale bar? Is absolute secrecy required? Moreover, contract interpretation principles such as those that govern

confidentiality agreements generally draw on state-law principles—would a breach of a confidentiality agreement in one state create on-sale bar implications in others? *Cf. Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001) (noting "the importance of having a uniform national rule regarding the on-sale bar").

In addition, because the on-sale bar has, until now, been consistently interpreted to extend to secret commercial sales, a contrary ruling in this case will create uncertainty into related areas of patent law. For instance, the "public use" doctrine has also been interpreted to apply to secret or non-informing uses. *See Egbert v. Lippmann*, 104 U.S. 333, 337-38 (1881) (holding that a claimed corset stay, used once and hidden from public view, invalidated the patent); *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 519-20 (2d Cir. 1946). Helsinn's position might unsettle that longstanding rule.

Helsinn's new on-sale rule would also invite uncertainty that would harm both generic and brand-name pharmaceutical companies. Patent litigation is already uncertain: current data shows that the chances of a generic manufacturer prevailing in a Hatch-Waxman suit is close to 50/50.[16] Helsinn's proposed rule would make the situation worse.

Neither generic and biosimilar manufacturers nor brand-name drug companies could reliably predict

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[16] RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* 4 (Jan. 15, 2010), http:// amlawdaily.typepad.com/pharmareport.pdf.

whether a particular sale is secret enough to invalidate a patent. Brand-name companies would be left with an unclear sense of the size of their markets given the potentially invalidating activity they have engaged in for post-AIA inventions. Meanwhile, generic and biosimilar manufacturers would be subject to two layers of uncertainty: factual uncertainty regarding the precise terms of a sale (which it could not learn until discovery) and legal uncertainty regarding how secret an agreement has to be to avoid the on-sale bar. This uncertainty will discourage patent litigation by manufacturers of generic and biosimilar medicines—which Congress sought to encourage in the Hatch-Waxman Act and Biologics Price Competition and Innovation Act—and discourage both investment and competition.

CONCLUSION

The judgment of the Federal Circuit should be affirmed.

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No. 17-1229

In the

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioners,

v.

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* AUSTIN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

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QUESTIONS PRESENTED

1. Whether, under the Leahy-Smith America Invents Act, an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention.

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae Austin Intellectual Property Law Association ("Austin IPLA") is a bar association located in Austin, Texas with approximately 250 members engaged in private and corporate practice across a wide range of industries and technologies. (*See* www.austin-ipla.org.) Austin IPLA members represent both the owners and users of intellectual property. Austin IPLA takes no position on the ultimate outcome of the parties' dispute, particularly whether an inventor's sale of an invention to a third party that is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention. Austin IPLA's sole interest is that the integrity of the Patent Act be maintained through consistent interpretation of statutes, doctrines, and intellectual property rights.

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than *amicus* and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. All parties to this dispute have consented to the filing of this brief.

SUMMARY OF THE ARGUMENT

The Federal Circuit's decision in *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.* leaves unanswered important questions regarding whether Congress intended to modify its understanding of the *quid pro quo* that is at the heart of the patent system. 855 F.3d 1356 (Fed. Cir. 2017). In the absence of express Congressional intent, the Federal Circuit chose to apply its pre-AIA case law to the post-AIA question of whether a sale of an invention, where the sale but not the invention became known to the public, barred patentability under post-AIA 35 U.S.C. § 102(a)(1). Because the AIA drastically shifted the whole patent system—transforming America from a first-to-invent to a first-to-file system, the Federal Circuit's reasoning not to deviate from its pre-AIA precedents may be misplaced.

The Federal Circuit's *Helsinn* decision also leaves unanswered the question of whether purely private sales made under a non-disclosure agreement (NDA), where neither knowledge of the sale or the invention becomes public, are a bar to patentability pursuant to 35 U.S.C. § 102(a)(1). Although this question is not directly before this court, by addressing whether Congress modified its understanding of the quid pro quo of patent law when it shifted America to a first-to-file system, this Court may provide much needed guidance to patent owners, potential licensees, and practitioners.

ARGUMENT

I. The Court Should Decide Whether Congress Intended to Shift Its Understanding of the *Quid Pro Quo* of Patent Law.

By moving the American patent system from first-to-invent to first-to-file, Congress may have also shifted its understanding of the quid pro quo of the patent system such that reliance on pre-AIA "on sale" bar precedent is no longer relevant.

Post-AIA Section 102(a) lists five independent conditions which could bar patentability:

-being "patented"

-being "described in a printed publication"

-being "in public use"

-being "on-sale"

-being "otherwise available to the public."

35 U.S.C. § 102(a)(1). Only the "on sale" condition fails to require public knowledge of the invention to be patented.

These conditions are similar to the conditions in pre-AIA § 102(b), which barred patentability if the invention was:

-"known by others in the country";

-"used by others in the country";

-"patented"; or

-"described in a publication"

"before the invention thereof by the applicant"; or if "more than one year prior to the date of the application," the invention was:

-"patented";

-"described in a printed publication";

-"in public use . . . in this country"; or

-"on sale . . . in this country".

35 U.S.C. § 102(a) and (b) (pre-AIA).

Because of the similarity between the two passages, in reaching its decision in *Helsinn*, the Federal Circuit turned to its pre-AIA precedents. *Helsinn* at 1367, n.7 (approvingly citing to its line of pre-AIA cases holding that even a private sale or offer for sale can be a barring event). The Federal Circuit also approvingly cited treatises that came to the same conclusion. *Id.*

Justifying its approach, the Federal Circuit noted that "[i]f Congress intended to work such a sweeping change to our on-sale bar jurisprudence and 'wished to repeal . . . [these prior] cases legislatively, it would do so by clear language.'" *Id.* at 1371 (citing to *Dir., OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 321 (1983)). However, the Federal Circuit seems to overlook that the AIA as a whole effectuated a sweeping change: transforming the American patent system from a first-to-invent system to a first-to-file system. Because this change was so fundamental, this Court should consider whether Congress needed to accompany it with an express statement of its intention to overrule the Federal Circuit's on-sale bar jurisprudence. At least, this Court should consider

whether the change in systems re-adjusted Congress' understanding of the *quid pro quo* of the Patent Act.

"The disclosure required by the Patent Act is the quid pro quo of the right to exclude." *JEM Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 US 124, 142 (2001) (internal quotations and citations omitted); *see also Kewanee Oil Co. v. Bicron Corp.*, 416 US 470, 480-81 (1974) ("In return for the right of exclusion—this "reward for inventions,"—the patent laws impose upon the inventor a requirement of disclosure.") (citations omitted). The Government thus will not grant a patent unless the inventor discloses his invention to the public, and an inventor may not remove an invention that is already a part of the public domain. *See, e.g.*, 35 U.S.C. § 102(b) (barring a patent if the inventor sold or offered to sell his invention more than one year prior to filing a patent application); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 6 (1966) ("Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available.")

Historically, inventors had to choose whether to protect their intellectual property through trade secret or patent law, but generally not both. *See Kewanee*, 416 U.S. at 490-92. Provisions, such as the pre-AIA on-sale bar prevented an inventor from choosing trade secret protection for years and switching to patent protection upon learning that a competitor had independently derived the trade secret. In the first-to-invent system, even if the competitor attempted to patent the invention, the inventor would be protected under the first-to-invent

system, since he would be able to defeat patentability by showing that he had known or used the invention in public first.

By switching to a first-to-file system, where the statute includes the incentive to be the first filed, the policies underlying the first-to-invent system may no longer be relevant. For example, in a first-to-file system where the inventor chose not to disclose his invention in exchange for exclusivity, should the system still reward him by allowing him to invalidate the invention of a second inventor? Or should the system allow him to exploit his invention through secret sales and grant him exclusivity for his invention as long as he is the first to disclose the invention through filing a patent application? Such questions directly implicate whether Congress' has altered the fundamental *quid pro quo* of patent law, and taking into consideration Congress' actions, this Court will help provide clarity to practitioners.

II. The Court Should Decide What Types of Private Agreements are Encompassed by the On-Sale Bar.

The current caselaw does not provide clarity about what types of private agreements would be included in the post-AIA on-sale bar, assuming that private agreements are included at all. This issue is raised by the Question Presented because the agreement at issue was a private Supply and Purchase Agreement that may implicate future products that have not been developed. Thus, under the Federal Circuit's holding in *Helsinn* there is no certainty for patent practitioners or patent owners

about the exact date that future products covered by such an agreement would have a potential on-sale bar.

Up until the Federal Circuit's *en banc* decision in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016), all types of private agreements were bars to patentability. For example, in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), the court held that a patentee's contract with a supplier to manufacture the product embodying an invention constituted a disqualifying "sale," even though the production activity and the invention remained secret. *See id.* at 1357. In *In re Caveney*, 761 F.2d 671 (Fed. Cir. 1985), the court upheld the application of the on-sale bar to an offer to sell the claimed invention to a single entity, even though the counterparty "kept the claimed invention secret from the purchasing public" and the sale activity was "kept secret from the trade." *Id.* at 674-675.

The question becomes when is "the claimed invention . . . on sale" per 35 U.S.C. § 102(a)(1)? This Court's decision in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998) provides some answers. In *Pfaff*, this Court established a two-prong test for determining whether an invention is "on sale," considering (1) whether the product was the subject of a commercial offer of sale and (2) whether the invention is ready for patenting. *See Pfaff*, 525 U.S. at 67. Therefore, technology which has not been developed yet does not meet this test, since an invention has to be "ready for patenting."

What happens when the decision is made at the company, for example by an engineer at the company, to include the technology that encompasses

the invention in one of the planned future semiconductor chips, and that future semiconductor chip is part of the multi-year agreement with the customer, for example the automotive company. Although no known case addresses this issue, it seems that at this point the invention meets the two-part *Pfaff* test and becomes "on sale" per 35 U.S.C. § 102(a)(1). Therefore, this internal decision to include the technology that includes the invention in the future product either marks a complete bar to patentability under § 102(a)(1), or if 35 U.S.C. § 102(b)(1)(A) applies, starts the ticking of the 1-year clock within which an application for a patent must be filed. It is unclear if these types of agreements, in combination with the decision to include the patented technology as a component of the product, actually put the patented technology on-sale or not.

Other questions regarding what types of private agreements are included in the on-sale bar to patentability also remain. For example, whether a private sales agreement for a product which includes the patented technology as a component, but where the sales agreement does even mention the patented technology, trigger the on-sale bar. Whether there are agreements that would not be bar to patentability when private, but become bars to patentability when they become public? What happens if a company reverses its decision and decides not to include the patentable technology in the future product after an agreement is signed. These questions lead to uncertainty for practitioners.

CONCLUSION

Respectfully submitted by amicus curiae Austin IPLA.

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August 30, 2018

No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* BAR ASSOCIATION OF THE DISTRICT OF COLUMBIA IN SUPPORT OF PETITIONER

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The Bar Association of the District of Columbia ("BADC") respectfully submits this brief as *amicus curiae* in support of petitioner.[1]

INTEREST OF THE AMICUS CURIAE

Founded in 1871, the BADC, a non-profit organization, is one of the oldest bar associations in the nation. The BADC and its members have a proud history of working closely with the judiciary, courts, the DC council, and the U.S. Congress on the administration of justice. The Intellectual Property Section ("IP Section") of the BADC draws its membership from individuals in government, industry, and private practice having an interest in intellectual property law including patent, trademark, and copyright law. The IP Section has a substantial interest in the adjudication of significant issues related to patent laws and submits *amicus curiae* briefs only when issues of significant importance arise. This case presents such an important issue. The Federal Circuit's interpretation of the Leahy-Smith America Invents Act ("AIA") and its failure to recognize the change that the AIA made to the on-sale bar will have an impact on many of the more than one million patentees who hold patents granted since the AIA has been in effect. It will also continue to cast a cloud of uncertainty over a countless number of patents that

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the amicus curiae or its counsel made a monetary contribution to its preparation or submission. All parties have consented to the filing of this brief.

will be issued in the future. This Court's guidance regarding the AIA's revision is of critical importance to the entire patent community.

SUMMARY OF ARGUMENT

This case is about an issue of critical importance to our nation's innovation-driven society. The Federal Circuit's failure to recognize the fundamental change in on-sale bar law under the AIA[2] will have the clearly unintended and damaging consequence of discouraging innovation. Its incorrect interpretation of the AIA on-sale bar discriminates against and penalizes small innovators as they compete with large companies with dedicated internal facilities. Large corporations employ a vertically integrated business model with their own in-house development and distribution facilities to carry out all of the necessary work, avoiding external development contracts that linger as hidden patent validity "landmines." Since large corporations do not need to contract with third parties to manufacture or distribute their goods, they are free to conduct preparations for distribution of a future product without concern that their actions will trigger the AIA on-sale bar.

Small companies, in comparison to their vertically integrated competitors, operate in a much different fashion and rely heavily on outsourcing development, manufacturing, and distribution activities to third parties. The Federal Circuit's application of the AIA on-sale bar to transactions where an innovator

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[2] Pub. L. No. 112-29, § 3(b), 125 Stat. 284, 285-86 (2011) (codified at 35 U.S.C. § 102(a)(1)).

contracts with a third-party distributor (who agrees to and does keep the claimed invention confidential) penalizes small companies that do not have the resources or facilities to develop and distribute their products in-house. This interpretation is inconsistent with the intent of the AIA.

As the number of startups and small companies is growing at a rapid rate, the business model has moved away from vertical integration and shifted to outsourcing capital-intensive functions such as manufacturing and distribution. For example, small pharmaceutical and biotechnology companies and products are becoming increasingly more common. In recent years, the majority of approved drug products originated at smaller pharmaceutical companies (64 percent in 2016). Outsourcing allows smaller companies to be more agile, efficient, and focused. If the Federal Circuit's decision is allowed to stand and the on-sale bar of the AIA is triggered by a patentee's outsourcing of distribution functions, companies driving innovation will be penalized. And the objectives of patent law under the Constitution—"[t]o promote the Progress of Science and the useful Arts"—will not be met. *See* U.S. Const., art. I, § 8, cl. 8. In order to protect innovation, ensure uniformity, and carry out the mandate of the U.S. Constitution, this Court should recognize the fundamental change of the on-sale bar under the AIA.

For the foregoing reasons, the BADC urges the Court to construe the on-sale bar under the AIA in a way that produces uniformity in its application and avoids inconsistent results. This Court should reverse the judgment below to prevent the Federal Circuit's

misinterpretation of the AIA from discouraging innovation and preventing important innovations from reaching the market.

ARGUMENT

I. The Federal Circuit's Decision Is Inconsistent with the Statutory Text

Not only does the Federal Circuit's decision have grave implications for small companies like Helsinn, but it also violates fundamental principles of statutory interpretation. The pre-AIA on-sale bar provided, in relevant part, that a patent could not be obtained for an invention that was "on sale in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. § 102(b) (2006). In sharp contrast, the on-sale bar provision under the AIA provides, in relevant part, that a patent cannot be obtained if "the claimed invention was patented, described in a printed publication, or in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention." 35 U.S.C. § 102(a)(1) (emphasis added). The AIA added the phrase "or otherwise available to the public" to the statute. As described in Helsinn's opening brief, and as the PTO and the AIA's sponsors have recognized, the AIA's text demonstrates that the phrase "otherwise available to the public" clarifies the scope of the preceding phrase "on sale." The AIA requires that a sale make an invention "available to the public."

The Federal Circuit's interpretation of the AIA on-sale bar fails to recognize that under the AIA, an offer for sale that does not make the claimed invention available to the public no longer triggers the on-sale

bar. Confidential distribution arrangements relating to how an invention will be distributed in the future are not the kind of activity that make the invention available to the public. In failing to account for this significant change in law, the Federal Circuit ignored this Court's admonition that "when Congress acts to amend a statute, [this] [C]ourt presumes [it] intends its amendment to have real and substantial effect." *Pierce Cty. v. Guillen*, 537 U.S. 129, 145 (2003) (quoting *Stone v. INS*, 514 U.S. 386, 397 (1995)). The Federal Circuit's interpretation does not give any effect to the new phrase in section 102(a)(1) ("otherwise available to the public") and therefore, it cannot be the proper construction of the statute. *Pierce*, 537 U.S. at 145 ("That reading gives the amendment no real and substantial effect and, accordingly, cannot be the proper understanding of the statute.") (internal quotations omitted). The "otherwise available to the public" phrase should be given its proper meaning and secret offers for sale should no longer implicate the AIA on-sale bar. The actions of Congress cannot be nullified by the Federal Circuit's decision here.

II. The Federal Circuit's Decision Will Have a Chilling Effect on Innovation

A. Small Innovators Are Important Contributors to Today's Economy

The patent laws need to protect the interests of inventors and create incentives for filing new patent applications in order to drive innovation. The benefit to the economy is not the only advantage that arises from protecting innovation: in exchange for a limited period of exclusivity, the public receives the benefit of the invention. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55,

63 (1998) ("[a]s we have often explained . . . the patent system represents a carefully crafted bargain that encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.") (internal cite omitted).

In today's economy, the corporate structure is rapidly changing. The number of startups and small pharmaceutical and biotechnology companies has greatly increased and these agile companies are making important advances in science and technology. For example, small pharmaceutical companies acquire drugs from other companies (like Helsinn did here) or academia and seek to commercialize them. *See, e.g.*, Pet. App. 79a. These companies, like Helsinn, do not typically have their own formulation research-and-development laboratories, and therefore they rely on third parties, such as contract research organizations ("CROs") and contract manufacturing organizations ("CMOs") to accomplish their goals. *Id.* In contrast, large pharmaceutical companies are typically vertically integrated, which means that they carry out all of their work in-house. This work includes drug discovery, preclinical research, clinical development, regulatory work, manufacturing, distribution, sales, and marketing.

The small pharmaceutical and biotechnology sectors have experienced growth over the years. A recent study found that the majority of drugs approved by the U.S. Food and Drug Administration ("FDA") (64 percent in 2016) were developed at smaller pharmaceutical companies. Jennifer Alsever, *Big Pharma Innovation in Small Places*, FORTUNE (May 13,

2016), http://fortune.com/2016/05/13/big-pharma-biotech-startups/; *see also* J.A. DiMasi et al., *Innovation in Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECONOMICS, 20, 31 (2016) (noting the growth of the small pharmaceutical sector). The biotechnology sector grew at a compounded annual rate of 3.7 percent between 2010 and 2016, from approximately $263 billion to a projected $293 billion. *2017 Global Life Sciences Outlook: Thriving in Today's Uncertain Market*, Deloitte, 2017. These statistics prove that small pharmaceutical and biotechnology companies are important contributors to driving innovation. As they continue to grow, the Federal Circuit's decision will continue to have the damaging consequence of discouraging innovation.

B. Concerns Regarding the AIA On-Sale Bar May Prevent Important Pharmaceutical and Biotechnology Products from Reaching the Market

1. Helsinn's Important Aloxi® Drug Product

Helsinn is a small, family-owned pharmaceutical company based in Switzerland. Pet. Br. 8. The patent at issue here (U.S. Patent No. 8,598,219) protects Helsinn's drug product Aloxi®, which helps improve the lives of cancer patients by reducing nausea and vomiting caused by chemotherapy treatment.[3] Pet. Br. 8. Bringing Aloxi® to the market was a very long and expensive process. At one point, the large

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[3] Aloxi® is a pharmaceutical composition containing palonosetron hydrochloride as the active ingredient. Pet. Br. 9.

pharmaceutical company (Roche) that Helsinn purchased the molecule from deemed the project too risky to pursue. Pet. 30-31. Helsinn took a risk and invested significant resources into developing the drug product that is now Aloxi®. Pet. Br. 9; Pet. App. 141a. The drug development process was not easy and Helsinn faced difficult challenges, such as developing a product that was stable enough that it did not degrade before it was finally given to patients suffering from the effects of chemotherapy. Pet. App. 95a-96a. Helsinn's persistence paid off and scientists found that lower concentrations of the active pharmaceutical ingredient promoted stability while still delivering a dose that was effective in combatting nausea and vomiting.

2. The Transaction at Issue Here

Helsinn, a family-owned company, did not have its own manufacturing or distribution facilities at the time it was developing its palonosetron product. *See* Pet. App. 34a, 79a. Around 1998, right before Helsinn began developing the product at issue, it had about 200-250 employees. Pet. App. 78a. Like many small companies that are not vertically integrated, it needed to outsource these capital-intensive activities to third parties. During the long and difficult drug development process, Helsinn needed to find a partner to share some of the risk it faced in developing the product. After an extensive search, it found MGI Pharma ("MGI"), a small Minnesota company. Pet. Br. 9.

Helsinn entered into a license agreement and a distribution arrangement with MGI. Pet. Br. 9. The agreements obligated MGI to make upfront payments to Helsinn if Helsinn's products received FDA approval.

The distribution arrangement provided for MGI to purchase palonosetron products from Helsinn, if the products received FDA approval. Pet. Br. 9. The agreements required MGI to keep proprietary knowledge relating to the products confidential. Pet. Br. 9-10. MGI adhered to its confidentiality obligations and in its SEC filings, redacted any information relating to the palonosetron formulations. Pet. Br. 10. The details regarding the formulations were also omitted from a joint press release announced by both parties. Pet. Br. 10. Information regarding the claimed invention was, therefore, not available to the public.

3. Distribution Arrangements Are Pre-Commercial Activity that Does Not Trigger the On-Sale Bar of the AIA

Distribution agreements constitute pre-commercial planning activities and should not trigger the on-sale bar of the AIA. They merely set up a framework for distribution of a product if and when it is approved. They do not make the invention available to the public. Here, Helsinn had not obtained FDA approval for its product at the time it entered into the agreement with MGI. Moreover, there was no guarantee that the FDA would approve Aloxi® at the time of contracting. Since Helsinn did not have its own in-house manufacturing and distribution facilities, it had to outsource these functions to third parties. It needed a plan in place so that it would have the resources to bring the drug to hospitals and patients in the future, if it did receive FDA approval. Neither Helsinn nor MGI could have sold the product to anyone because the FDA had not issued its approval at the time the parties entered into

the agreement. The transaction at issue in Helsinn constituted pre-commercial activity that was done to prepare for later commercialization of the product (after it was approved by the FDA). *See In re Kollar*, 286 F.3d 1326, 1334 (Fed. Cir. 2002) (holding that "the pre-commercialization process aimed at making the invention commercial" does not implicate the on-sale bar).

Judge O'Malley acknowledged that "[i]t is fair to question whether distribution agreements *should* fall within the scope of the on-sale bar . . . ." Pet. App. 15a (O'Malley, J., concurring in the denial of panel rehearing) (emphasis in original). She described that the purpose of entering into distribution agreements is to "mak[e] preparations to sell products to the public in the *future*" and noted that "these agreements do not themselves effectuate consummated sales to end users." *Id.* (emphasis in original). Concerns regarding application of the on-sale bar based on the patentee's preparation and planning activities predate the AIA:

> The on-sale bar's applicability to commercial agreements entered into for the purpose of preparing to make future sales has provoked criticism long before Helsinn. *Cf. McCreery Eng'g Co. v. Mass. Fan Co.*, 195 F. 498, 502 (1st Cir. 1912) (noting that "there is reason to doubt whether an offer to deliver an article at a future time is in substance a putting on sale before the time of actual delivery").

Pet. App. 16a. Moreover, in a case involving the pre-AIA on-sale bar, Judge Reyna voiced concerns for small companies that need to outsource: "My greatest concerns involve the implications this case will have for

future innovators, most notably small enterprises and individual inventors who lack in-house prototyping and fabricating capabilities." *Hamilton Beach Brands, Inc. v. Sunbeam Prods.*, 726 F.3d 1370, 1381 (Fed. Cir. 2013) (Reyna, J., dissenting).

If small pharmaceutical and biotechnology companies face the risk that their contractual distribution agreements with third parties may years later trigger the AIA on-sale bar, it could prevent them from bringing new products to the public. Many drugs—including Aloxi®—are discovered by small pharmaceutical companies. Small companies frequently need the assistance of third parties to develop and distribute their products. Furthermore, many small companies, such as Helsinn, need to work with a third party to obtain funding to develop their products or face the risk of running out of money to complete the project. As Judge O'Malley recognized: "there is often a need to make distribution agreements public to induce investors to supply funding for product development." Pet. App. 15a. Moreover, small pharmaceutical and biotechnology companies may not be able to recoup their research and development investment if prior distribution arrangements are later found to invalidate patents that cover important products. The mounting expenses could cause these small companies to face dissolution or bankruptcy.

As the number of small innovator companies grows, their ability to work with third parties without fear of running afoul of the on-sale bar becomes increasingly important. If the scope of the AIA on-sale bar is not clear, small companies may not invest in risky projects that could provide life changing or life saving products.

In order to promote innovation and protect the interests of all inventors (including small ones), this Court should recognize the fundamental change of the on-sale bar under the AIA.

III. The Federal Circuit's Decision Results in the On-Sale Bar Being Inconsistently Applied

While a vertically integrated corporation can make preparations for development and distribution of a product in-house without concern that these activities would invoke the AIA's on-sale bar, a small company (such as Helsinn) cannot. The different results—from application of the same statute—cannot be reconciled.

A. Small Corporations Without In-House Distribution Facilities Will Be Disadvantaged if This Court Does Not Correct the Federal Circuit's Erroneous Interpretation of the AIA On-Sale Bar

With the business structure shifting away from vertical integration (*see supra*), outsourcing will become a mandatory part of doing business. In order to survive and compete, small companies will need to rely heavily on a number of third-party providers. CROs and CMOs will help them with their research-and-development projects. They will also need third-party distributors and outside investors. By simply contracting with a distributor prior to the critical date, a patentee could trigger the AIA on-sale bar and years later lose the patent protecting its valuable invention.

Large corporations, however, do not have to hire third parties to help with development and distribution. They have these resources in-house and

can rely on their own warehouses and distribution channels throughout the country. Vertically integrated companies do not need to contract with distributors and therefore do not typically engage in activities resulting in an offer for sale of the claimed invention.

The Federal Circuit's decision penalizes small pharmaceutical companies for outsourcing and places them in the difficult position of losing their patent rights or creating their own in-house distribution facilities. Doing so would greatly increase costs and divert economic resources away from developing important new drug products. Amy V. Beekman and Richard B. Robinson, *Supplier Partnerships and the Small, High-Growth Firm: Selecting for Success*, 42(1) J. SMALL BUSINESS MANAGEMENT, 59, 72 (2004) ("longer-term [supplier] relationships offer significant benefits and [] these benefits are enduring . . . In the sample, 86 percent of the 91 [pharmaceutical] firms had sales that grew 15 percent or greater every year during a three-year period . . . ."). Furthermore, the costs to bring new drugs to market are approximately $2.6-2.9 billion dollars. J.A. DiMasi, 47 J. HEALTH ECONOMICS at 31 (the cost is approximately $2.9 billion when estimated R&D costs incurred after initial approval are added); Jerry Avorn, *The $2.6 Billion Pill—Methodologic and Policy Considerations*, 372(20) NEW ENG. J. MED. 1877, 1877 (2015). Since these costs do not vary significantly between large and small pharmaceutical companies, saving costs becomes of great importance to the small innovators. *See* DiMasi, 47 J. HEALTH ECONOMICS at 29.

To ensure that a contractual relationship with a third-party distributor would not trigger the on-sale

bar of the AIA, small companies would have to file patent applications within one year of entering such an agreement. While at first glance this does not seem too difficult, it ignores the impracticality, expense, and burden this would place on small innovators. First, patent applications for all projects—whether or not they are successful—will have to be filed. Potential new products fail to reach the market for a number of reasons, including lack of commercial viability and failure to achieve the desired results.

Second, requiring small companies to file patent applications on all proposed inventions could cost a great deal of money. Justice Breyer noted in *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923 (2016), that costs like these can prevent an innovator from getting a small business up and running. *See infra*. Moreover, this added burden is inconsistent with the business model of small companies as they strive to reduce costs and operate efficiently. Filing patent applications on projects that do not even end up being successful will waste the precious resources of small businesses. Drug products like Aloxi®, which improve the quality of life of cancer patients, may not be able to make it to the market. The general public will be harmed and will miss out on important products that not only save lives, but improve the quality of life, often on a daily basis.

B. This Court Should Interpret the AIA On-Sale Bar to Maintain a Consistent and Uniform Application

The on-sale bar of the AIA should be interpreted in a way that ensures a uniform application. Small companies should not be penalized and face additional

burdens that do not affect vertically integrated companies. In a recent patent case, this Court considered the harm to small innovators in construing Section 284 of the Patent Act. *Halo Elecs.*, 136 S. Ct. at 1936 (Breyer, J., concurring). In *Halo Electronics*, Justice Breyer agreed with the majority and filed a concurring opinion to express his understanding of the limits imposed on Section 284 that "help produce uniformity in its application and maintain its consistency with the basic objectives of patent law." *Id.* at 1936. Justice Breyer considered the interests of small businesses and innovators in agreeing with the majority's interpretation of Section 284:

> The Court does not weaken this rule through its interpretation of §284. Nor should it. It may well be expensive to obtain an opinion of counsel. See Brief for Public Knowledge et al. as Amici Curiae 9 ("[O]pinion[s] [of counsel] could easily cost up to $100,000 per patent"); Brief for Internet Companies as Amici Curiae 13 (such opinions cost "tens of thousands of dollars"). *Such costs can prevent an innovator from getting a small business up and running.*

Id. (emphasis added). Justice Breyer recognized the harm that could result from requiring small businesses to obtain an opinion of counsel. The resources and expense required to do so could discourage innovation and prevent a small business from getting off the ground. The Federal Circuit's erroneous interpretation of the on-sale bar directly implicates these concerns. Inconsistent application of the AIA's on-sale bar could discourage lawful innovation and place additional

monetary burdens on small innovators who are trying to get small companies up and running.

This Court should reverse the judgment below to prevent the Federal Circuit's misinterpretation of the AIA from discouraging innovation and preventing important innovations from reaching the market.

IV. The Court Has Long Recognized the Public-Disclosure Underpinnings of the On-Sale Bar

Even in the absence of a statutory requirement, the Court's pre-AIA rulings recognized that on-sale activities were connected to public disclosure. *See Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 148-49 (1989) ("From the Patent Act of 1790 to the present day the *public sale* of an unpatented article has acted as a complete bar to federal protection of the idea embodied in the article thus placed in *public commerce*.") (emphases added).

In *Pennock v. Dialogue*, 27 U.S. 1 (1829), the Court held that an inventor loses his right to a patent "if he suffers the thing invented to go into public use, or to be *publicly sold for use*, before he makes application for a patent. His voluntary act or acquiescence in the *public sale* and use is an abandonment of his right." *Id.* at 23-24 (emphases added). In describing its decision in Pennock, the Court later observed "that under the common law of England, letters patent were unavailable for the protection of articles in public commerce at the time of the application, and that this same doctrine was immediately embodied in the first patent laws passed in this country." *Bonito Boats*, 489 U.S. at 149.

Following *Pennock*, the Court's treatment of the on-sale bar remained tethered to public disclosure. In *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1877), the Court noted that "if the inventor allows his machine to be used by other persons generally, either with or without compensation, or if it is, with his consent, put on sale for such use, then it will be in public use and on *public sale*, within the meaning of the law." *Id.* at 135.

Thus, as the Federal Circuit explained, "the early public-use and on-sale statutory restrictions were premised on the principle that 'no invention, which has already passed from the control of the inventor into the possession of the public is entitled to protection.'" *Medicines Company v. Hospira, Inc.*, 827 F.3d 1363, 1371 (Fed. Cir. 2016) (*en banc*) (quoting 1 William C. Robinson, *The Law of Patents for Useful Inventions* § 71, 109 (1890)). In *Pfaff*, the Court once again reaffirmed this principle when it recognized that the "reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar." 525 U.S. at 64.

CONCLUSION

The judgment of the Federal Circuit should be reversed.

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No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

THE BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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STATEMENT OF INTEREST OF AMICUS CURIAE

The Biotechnology Innovation Organization ("BIO") is the principal trade association representing the biotechnology industry. BIO has more than 1,000 members, which span the for-profit and non-profit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. Approximately 90% of BIO's corporate members are small or mid-size enterprises that have annual revenues of under $25 million, and that count their patents among their most valuable business assets. Because modern biotechnological products commonly involve lengthy, resource and investment-intensive development periods, BIO's members depend heavily on robust patent rights and a fair system for adjudicating their validity. Accordingly, certainty regarding the types of transactions and what must be publicly disclosed about those transactions to qualify as invalidating activities under the on-sale bar of the America Invents Act (AIA) is of great importance to BIO.[1]

SUMMARY OF THE ARGUMENT

The 2011 Amendments to the Patent Act converted the U.S. patent system from a first-to-invent to a first-to-file system, thereby necessitating certain fine tuning in order to achieve Congress's goal. In this vein, Congress

1. BIO has no stake in the result of this appeal. Pursuant to Supreme Court Rule 37, all parties have consented in writing to the filing of this brief. No party other than the *amicus curiae*, its members, or its counsel, have authored the brief in whole or in part or made any monetary contribution intended to fund its preparation or submission.

made important changes to the prior art provisions of 35 U.S.C. § 102, broadening the territorial reach of prior art and limiting its scope to that which makes the invention "available to the public." This was a sensical balance that flowed from the first-to-file nature of the amendments: when the yardstick for patenting is whether someone files an application before another, secret disclosures that could have established prior inventorship under the old system are no longer relevant. Instead, because the emphasis is now on who files first, the prior art inquiry should—and under Petitioner's interpretation now does—inquire into what was available to the public.

As correctly urged by Petitioner, "prior art" defined under § 102 must make the invention available to the public to destroy novelty. This is compelled by the plain language of the 2011 Amendments and is the only interpretation that implements Congress's policy goals. But the Court of Appeals concluded otherwise, without construing the statutory language, and without explaining what effect should be given to the amended language requiring that "the claimed invention was ... on sale, or otherwise available to the public." By avoiding discussion of this text, and by ruling that "if the existence of the sale is public, the details of the invention need not be publicly disclosed," *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017), the Federal Circuit created not only unmanageable uncertainty about the validity of patents, but also an unnatural reading of § 102(a). The America Invents Act ("AIA") Pub. L. 112-29-Sept. 16, 2011 requires that knowledge of the "claimed invention," not knowledge of the sale, be "otherwise available to the public."

A requirement that an invention must have been made available to the public in order to have prior art effect follows from a natural reading of 35 U.S.C. § 102(a)(1) and, contrary to Respondent's arguments, creates no tension with the "grace period" provisions at § 102(b)(1). Also contrary to Respondent's arguments, adopting a public-availability requirement for prior art would in no way sweep away decades of lower court caselaw or overturn this Court's precedent.

No policy purpose is served by letting the lower court opinion stand. To the contrary, the decision conflicts with Congress' stated policy goals, including substantive harmonization, and creating more predictability for businesses and the public. If the Federal Circuit decision stands, patents will be denied to deserving inventors who could not have been aware of invalidating business transactions, with no attendant benefits to the public. This effect is compounded by the expansion of the scope of such secret prior art to the rest of the world. Because the USPTO policy under the AIA has been consistent with Petitioner's interpretation of § 102(a), issued patents are also at risk.

The lower court's decision is particularly detrimental to research and development intensive businesses that engage in partnered agreements, or that use expert contractors for specialty services. In biotechnology, a majority of the new product development pipeline is held by small companies that depend on development and investment partnerships that may need to be undertaken before a patent application is filed. In instances where, as here, a partnering transaction is undertaken in a clearly pre-commercial context, involving a product under

development that requires further investment before it can be marketed, it cannot be said that the patentee engaged in premature commercial exploitation of his invention, or unduly extended his right to exclude. The Court should reverse.

ARGUMENT

I. The Court Should Reverse and Require that Placing an Invention On Sale Constitutes Prior Art Only When the Invention is Thereby Made Available to the Public.

As this Court has long emphasized "the starting point for interpreting a statute is the language of the statute itself." *Consumer Product Safety Commission v. GTE Sylvania, Inc.*, 447 U.S. 102, 108 (1980). Yet, the court below decided against this approach. This Court therefore has the opportunity to provide clarity on the on-sale bar embodied in 35 U.S.C. § 102, as amended in 2011 by the AIA. And as Petitioner and amicus respectfully submit, under the proper interpretation of the statute, a commercial transaction that does not inform the public about the claimed invention, nor make the invention available to the public, does not constitute prior art under the 2011 amendments to 35 U.S.C. § 102.

(a) Significant Ambiguities Created by the Court of Appeals' Atextual Interpretation of the AIA Require Resolution through Statutory Construction

The Court of Appeals declined to engage in any statutory construction of the 2011 amendments to 35

U.S.C. § 102, even though statutory construction was central to the district court holding and necessary to the disposition of the case. The amendments to 35 U.S.C. § 102 are significant, substantive, and generated more legislative commentary than any other section of the AIA. *See* J. Matal, A Guide to the Legislative History of the America Invents Act: Part I of II, 21 Fed. Cir. B.J., 435, at 449 (2012). In such a case, statutory construction is necessary.

Congress made several important changes to the language of § 102. Prior to the AIA, prior art consisting of patents, printed publications, prior use, and on-sale activities were spread over 35 U.S.C. § 102(a) and (b). In enacting the AIA, Congress chose to group these prior art categories into a single provision in § 102(a), followed by the addition of the previously-unseen modifier, "or otherwise available to the public." The Court of Appeals acknowledged that Helsinn's argument relied on this new language, 855 F.3d, at 1368, yet, rather than construing it, the Court of Appeals declined to give it any weight because it would "work a foundational change" to the on-sale bar, *Helsinn*, 855 F.3d, at 1369, thus leaving the import of the new modifier unclear.

While the Court of Appeals declined to say that the AIA modifies any aspect of its caselaw, it balked at saying that it does not. On the one hand, the panel's analysis contains an implicit acknowledgement that the AIA might incorporate a public disclosure requirement that modifies the lower court's on-sale caselaw in some unstated way, as shown by the panel's repeated emphasis on the content of public press releases, MGI's 8-K, and previously available public information. 855 F.3d at 1369-70. The panel's

holding that "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed," *Id.*, at 1369 indicates the same. Notably, *before the AIA*, public knowledge of the existence of a sale was not relevant to whether a commercial sale had prior art effect or not. *See, e.g., In Re Caveney*, 761 F.2d 671, 675 (Fed. Cir. 1985); *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355 (Fed. Cir. 2001).

While the lower court's reasoning thus suggests that under the AIA a completely confidential business transaction would not operate as patent-defeating prior art, this is not necessarily so. The Court of Appeals unhelpfully warns that even entirely secret commercial sales may continue to have a prior art effect under its caselaw in the future, just as would have been the case before the AIA. *Helsinn*, 855 F.3d 1356, 1369 and FN 7.

Judge O'Malley's opinion concurring from denial of *en banc* rehearing does little to clarify the uncertainty caused by the panel's hedging. Judge O'Malley writes:

> [We did] not suggest that publicly announced agreements will always trigger the on-sale bar, nor [did we] suggest that secret sales never will. As we explained in *Medicines*, the confidential nature of a transaction is just one of several factors for determining whether the transaction rises to the level of a commercial sale such that the on-sale bar would apply.

Pet. App. at 4a-5a. Judge O'Malley's statement, while correct, distracts from the main issue of this case. The critical question is not how to determine when a

transaction "rises to the level of a commercial sale." The critical question is how to determine when a commercial sale rises to the level of prior art.

(b) Judge O'Malley's Proposed Statutory Construction Does Not Support a Proposition that a Sale can have Prior Art Effect if it Does Not Make the Invention Available to the Public.

The only textual analysis of the 2011 amendments to 35 U.S.C. § 102 in the court below is found in Judge O'Malley's concurrence from denial of *en banc* rehearing,[2] in which Judge O'Malley explains that the words "otherwise available to the public" in section 102(a)(1) do not modify the preceding clauses. Pet. App. at 8a-9a. For support, Judge O'Malley points to the provisions at § 102(b)(1)(B), which juxtapose the terms "disclosure" and "publicly disclosed," thereby suggesting that not all prior art disclosures are necessarily "public."

This interpretation reads too much into section 102(b)(1)(B). The relevant section provides:

> (b) Exceptions.—
>
> > (1) [...] A disclosure made 1 year or less before the effective filing date of a claimed invention **shall not be prior art to the claimed invention under subsection (a)(1)** if— [...]

2. Judge O'Malley's analysis was not part of the precedential panel opinion, and it is unknown whether the other panel members share her reasoning.

> (B) the subject matter disclosed had, **before such disclosure, been publicly disclosed** by the inventor [...].

(*emphasis added*). Judge O'Malley's interpretation relies on a fundamental flaw: she conflates the word "prior art" with "disclosure." Pet. App. at 11a ("all prior art events—i.e., all 'disclosures'"); *see also* Respondent's Brief Opposing Certiorari at 26 ("Because disclosures means all types of prior art—includ[ing] some that are not public.") (internal quotations and citations omitted). But not every disclosure is also prior art. For example, the mere sharing of the details of an invention between prospective business partners under an obligation of confidentiality would constitute a disclosure, but would not fall into any of the prior art categories of § 102(a)(1). Likewise, subject matter appearing in a patent application can constitute a "disclosure," 35 U.S.C. § 102(b)(2), but it would not be prior art under § 102(a)(2) if the patent application never matured into a patent and was never published or deemed published.

Thus, Congress's use of different words, "disclosure" and "prior art," shows that the two are not coextensive.[3]

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3. *See also* 157 Cong. Rec. S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Leahy) ("Indeed. . . subsection 102(b)(1)(A), as written, was deliberately couched in broader terms than subsection 102(a)(1). This means that any disclosure by the inventor whatsoever, whether or not in a form that resulted in the disclosure being available to the public, is wholly disregarded as prior art."); (statement of Senator Hatch) ("Indeed, a disclosure that does not satisfy the requirements to be prior art under §102(a), nonetheless constitutes a disclosure that is fully protected under the more inclusive language of § 102(b).").

Congress amended § 102(b) to specify what kind of event would not constitute patent-defeating prior art if it occurred within one year before the invention's effective filing date, referred to as the "grace period." Section 102(b)(1)(B) does not address whether prior art under the AIA must be publicly available or not, although a reasonable reading lends support for the proposition that Congress intended prior art to be publicly available, as explained below. And on the simplest level, a reading of subsections 102(a)(1) and (b)(1) together reasonably stands only for the proposition that **all prior art events are disclosures, but not all disclosures are prior art.**

Section 102(b)(1) provides:

> A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under subsection (a)(1) if— [...]

This sentence confirms that not all "disclosures" matter for purposes of the grace period – disclosures of the invention are relevant only if they would constitute "prior art under subsection (a)(1)," that is, an instance of patenting, printed publication, public use, on sale, or otherwise being made available to the public. 35 U.S.C. § 102(a)(1). Other disclosures that do not constitute "prior art ... under subsection (a)(1)" (for example a confidential exchange of technical information between prospective business partners) are of course irrelevant, because they are immaterial for the patentability of a subsequent patent application, and the patent applicant would have no need to invoke a grace period.

Subparagraphs (A) and (B) of § 102(b)(1) then permit the patent applicant to disqualify those disclosures that would constitute prior art under § 102(a)(1) and that were made one year or less before the effective filing date. Subparagraph (A) disqualifies disclosures of the inventor whereas subparagraph (B) disqualifies disclosures of someone other than the inventor. Under § 102(b)(1)(A), the inventor's own disclosures (however made) during the year prior to filing are not prior art to her own patent application. Thus the only disclosures that can still be removed as prior art by subparagraph (B) during the year prior to filing are a third party's disclosures.

The fact that § 102(a)(1)(B) addresses disclosures by third parties has important implications for construing the AIA's prior art provisions. Subparagraph (B) provides that a prior art disclosure made one year or less before the filing of the patent application is disqualified as prior art if "the subject matter disclosed [by the third party] had, before such [third-party] disclosure, been publicly disclosed by the inventor ... ." Critically, § 102(a)(1)(B) does not refer to these third party disclosures as "public disclosures." In fact, Judge O'Malley's interpretation hinges on the juxtaposition of "disclosures" (which can emanate from third parties and, under her reading, be non-public) and "public disclosures" (which must be the inventor's).

Under Judge O'Malley's interpretation, if a sale that does not make the invention available to the public can be prior art, such a non-public sale *between third parties* would necessarily create prior art against a subsequent unrelated patent applicant. If that confidential third-party sale occurred one year or less before the

application date, the unrelated later patent applicant can attempt to disqualify it from being prior art under § 102(a)(1)(B), assuming that applicant would somehow learn of the sale. If the secret sale between third parties occurred more than one year before the application date, it would constitute an absolute bar against the unrelated patent applicant.

To provide an example of the untenable results that would follow from Judge O'Malley's and Respondent's interpretation, assume that a Chinese and a Japanese company transact confidential business in Hong Kong. An exclusive, confidential sale of the invention takes place, and no technical details of the invention are made public. Subsequently, an unrelated U.S. patent applicant who independently invented the invention applies for a patent in the USPTO. The applicant (and the patent examiner) would have no way of knowing that a prior art event had occurred,[4] and in all likelihood an invalid patent would issue.

But, it has been asked, if Congress intended all prior art to be publicly available, why did Congress specify in § 102(a)(1)(B) that only *public* disclosures by the patent applicant would be sufficient to remove the prior art effect of a third party disclosure? In other words, if all "disclosures" are public anyway, would not the word "publicly" be superfluous?

4. The AIA removed all geographic restrictions from the scope of prior art. Thus, if a confidential sale can constitute prior art if conducted in the US, it must do so if conducted in Hong Kong.

Properly construed, a public availability requirement for all prior art would not render any words superfluous in subparagraph (B). Subparagraph (B) provides that a third-party disclosure that qualifies as prior art, if it occurs one year or less before filing, can be antedated by the applicant's own public disclosure. But subparagraph (B) does not otherwise specify when that antedating disclosure must occur. For example, a patent applicant could properly disqualify a third party's printed publication of the claimed invention made one year or less before the effective filing date with a public disclosure the applicant made five years before the effective filing date. Of course that would not do the applicant much good, because her own public disclosure, made so long before she applied for a patent, would itself constitute prior art against her patent application.

And therein lies the crux. Because not every conceivable disclosure the applicant might have made is necessarily also prior art, the addition of the word "publicly" ensures that the applicant's antedating disclosure would *itself* have prior art effect, as it must in order to avoid untenable results. For example, absent a strict requirement for "public" disclosure, under the plain terms of § 102(a)(1)(B) an applicant could secretly disclose her invention in ways that do not constitute prior art, wait indefinitely until someone else discloses the invention in a form that *does* constitute prior art, and then wait another whole year before filing a patent application.

Thus, Congress's choice of the terms "disclosure" and "publicly disclosed" in § 102(b)(1)(B) can most simply and reasonably be explained as an effort to ensure that the AIA's grace period and prior art provisions work together

harmoniously without producing aberrant results. If care is taken to not conflate the terms "prior art" and "disclosure," Congress's choice of words makes perfect sense under Petitioner's (and the USPTO's) interpretation of publicly-available post-AIA prior art. In contrast, if Respondent's interpretation is adopted, § 102(b)(1)(B) would create a strong implication that Congress would have wanted to create a new class of secret (and global) prior art that operates against unrelated subsequent patent applicants who were never a party to any confidential prior sales or secret commercial uses.

(c) Reversal Here Will Not Fundamentally Affect Prior On-Sale Jurisprudence.

Petitioner's interpretation of 35 U.S.C § 102(a) will not render centuries of prior on-sale jurisprudence inapplicable. The Federal Circuit has developed comprehensive guidance on whether a transaction qualifies as a commercial sale or offer for sale, involving legally and factually complicated questions of offer, acceptance, and contract formation; of delivery and payment terms; and whether the object of such a sale was sufficiently developed to qualify as a complete invention, ready for patenting. This body of caselaw continues to be applicable because the new § 102(a) still requires courts to engage in all the same inquiries. Only after these elements are established would courts additionally now ask: "and did this commercial sale make the invention available to the public?" Congress understood that, after the AIA, a transaction will still need to qualify as a commercial sale, the date of the sale will still need to be determined, and the invention will still need to be found ready for patenting. This was good reason to retain the well-established words "on sale" in the new § 102(a).

Thus, the meaning courts have given to the words "on sale" for over a century remains largely undisturbed by the AIA. Likewise, nothing in the AIA abrogates this Court's seminal guidance in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), establishing the two principal conditions: (1) an invention must be the subject of a commercial offer for sale, and (2) the invention need not be reduced to practice so long as it is ready for patenting. Properly viewed, the 2011 amendments to 35 U.S.C. § 102 merely specify a third condition, public availability, without displacing the other two.

Nor is it certain, or even likely, that the explicit inclusion of a public-availability requirement would otherwise disturb the results this Court reached in past cases where an inventor exploited his invention long before applying for a patent. For example, in the seminal case of *Pennock v. Dialogue*, 27 U.S. 1 (1829), the validity of an 1818 patent for an improvement in making pressure-resistant leather hoses was at issue.[5] As was typical for U.S. patents prior to 1836, the patent likely did not

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5. Respondent has inaccurately characterized the 1818 Pennock and Sellers patent as "claim[ing] a process of making hose with pressure-resistant joints. The joints did not reveal the process." (Resp. br. opposing cert, at 5)(Internal citations omitted). This is unsupported and almost certainly incorrect. First, as a pre-1836 patent, the patent was unlikely to have contained a "claim," and, as the *Pennock* circuit court opinion makes clear, 19 F. Cas. 171 (C.C.E.D. Pa. 1825), the patent was not understood to be limited to just the manufacturing process. This is also apparent in Justice Story's opinion. Second, there is nothing in the Court's or the circuit court's opinion to suggest that an inspection of the improved hose would not have revealed the process by which it was made.

contain claims, and its scope of protection would have been understood to protect not only the specified process for making leather hose but also the improved hose so made. See *Pennock v. Dialogue*, 19 F. Cas. 171 at 173 (referring to "the hose for which this patent was granted," and referring to the hose as "the article so publicly used, and afterwards patented"). During the seven years preceding the application for patent, the patentee had authorized a third party to commercially manufacture and sell 13,000 feet of hose to various purchasers. 27 U.S. at 9. The authorized manufacturer was under no apparent obligation of confidentiality. Id. at 1. It was undisputed that the invention was openly available to the public, and nothing in the *Pennock* opinions indicates that there was anything non-public about the manufacture or sales of the improved hose.

Similarly, in *Pfaff* it is not at all clear whether the sale that occurred in that case would be deemed public or non-public in a post-AIA setting. The Court was focused on whether the invention had to have been reduced to practice before the critical date in order for the sale to have prior art effect, not on whether Pfaff made his invention available to the public. Neither the Court's opinion nor those of the lower courts indicate that the circumstances of Pfaff's sale were necessarily confidential, non-public, or exclusive.

Nor does the occurrence of only one sale to one buyer in *Pfaff* mean that the sale would necessarily be deemed non-public. Custom-designed products, such as the one in *Pfaff*, or those that are made to exacting buyer specifications under, *e.g.*, Government defense or aerospace procurement contracts, would be expected to

have very small – even single-buyer – markets. Thus, just like public use by one user can be enough to trigger the public use bar, *Egbert v. Lippmann*, 104 U.S. 333 (1881),[6] a public sale to the one (and only) buyer of a product could be enough to trigger the on-sale bar.[7] At any rate, such questions are better left for future caselaw development, and it is unnecessary to speculate about the hypothetical outcome when *Pfaff* is applied to post-AIA scenarios. It suffices that the holding of *Pfaff* would remain undisturbed if Petitioner's interpretation of publicly-available prior art were adopted.

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6. To the extent it could be argued that a public-availability requirement for prior art would overturn the Court's decision in *Egbert*, that concern, too, is misplaced. The *Egbert* Court acknowledged that the patented corset springs may have been capable of use "only where they cannot be seen or observed by the public eye." In this respect, the *Egbert* invention is similar to a patented internal component part of a machine, a patented implanted medical device, or myriad other inventions in widespread daily use today or then. Mere unobservability in public use does not make such an invention unavailable to the public. More importantly, it was undisputed that Ms. Egbert was gifted the inventive corsets with no restriction of confidentiality or any other condition, that she used them only for their ordinary purpose, and was free to regift, sell, demonstrate or replicate them. The inventor himself apparently demonstrated the invention on occasion. *Egbert v. Lippmann*, 104 U.S. at 335.

7. Conversely, an invention need not necessarily be deemed unavailable to the public when all sales activities are kept confidential. For example, where it is apparent that a seller of a specialty product is willing to meet market demand for that product and to supply all buyers, but requires all buyers to sign confidentiality agreements, such a seller could nevertheless be deemed to make the invention available to the public.

II. The Lower Court's Decision Has Extraordinary Extraterritorial Implications That Were Likely Unintended by Congress.

Congress eliminated the pre-AIA requirement that an invalidating public use or sale occur "in this country." Prior to the AIA, the types of prior art embodied in 35 U.S.C. § 102(a) and (b) could be grouped into two categories: (1) patents and printed publications, and (2) knowledge, use, and on-sale activities. Category (1) prior art could exist "in this or a foreign country" whereas category (2) prior art was explicitly limited to those activities occurring "in this country." Foreign sales, use, and knowledge did not qualify. Thus, for over 100 years the policy of the on-sale bar was concerned with the domestic market and the interests of the American public. In harmonizing United States patent law with international practices through the AIA, Congress removed territorial restrictions on category (2) prior art.

The Federal Circuit's decision elevates purely foreign conduct to have a negative effect on the patentability of inventions made in this country, contrary to law. By including within the ambit of § 102(a)'s on-sale bar, commercial activity that does not convey an invention to the public, the Court of Appeals' decision for the first time extends a patent-defeating effect to foreign conduct having no nexus with, and being undetectable from, the United States.

But the result of the Federal Circuit's decision is at odds with the legislative history. Congress removed all territorial restrictions on prior art from § 102(a), meaning that prior art references arising anywhere in the world can

invalidate patents. Only two rationales are relevant to the "otherwise available to the public" inquiry: (i) Congress meant to make prior art global, but publicly accessible, or (ii) Congress meant to preserve secret prior art, but make it global. The legislative history includes support for only one interpretation. This is not an instance of competing legislator narratives and contradictory Congressional statements. Both the House and Senate Reports, for example, state plainly that Congress intended prior art under section 102(a) to be art that is "available to the public." *See* H.R. Rep. No. 112-98, at 42, 43 (2011); S. Rep. No. 110-259, at 9, 32 (2008).

No public policy is served by the result of the Court of Appeal's decision, indicating that it was not intended by Congress. The rationale underpinning the pre-AIA on-sale bar was to prevent products long on sale in this country from being later withdrawn from the public by delinquent patenting. *See Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148-49 (1989). Similarly, courts were concerned that secret commercialization would permit an inventor to exploit his invention for an extended period of time before filing for patent protection, effectively extending his period of exclusivity to the detriment of the public. *See, e.g., Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 517 (2d Cir. 1946). But secret foreign sales do not implicate either of these concerns. For example, a non-public transaction between Japanese and Korean companies in Seoul, without more, does not impact what goods are available to American consumers, nor does it have any relevance to an unknowing domestic inventor's likelihood of obtaining patent protection.

Indeed, the Federal Circuit's ruling conflicts with United States patent law's focus on how a patentee orders his affairs, not the unknowable activities of third parties. This Court and the Federal Circuit have focused on the concern that the **patent applicant** will delay his patent filing in order to commercially profit from his invention beyond the statutory term. As expressed in *Pfaff*, the patent laws seek to protect **"the inventor's right** to control whether and when he may patent his invention." *Pfaff*, 525 U.S. at 65 (***emphasis added***). And even in other contexts, such as patent exhaustion, this Court has explained that it is the patentee's own decisions that determine when his rights will be extinguished. *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523, 1537 (2017). To be sure, foreign activities that make inventions available to the public are relevant to United States patent law in an age of the internet, borderless social media, and international online retail sales. But there is no statutory basis for our patent laws to suddenly focus on secret foreign activities that inherently cannot affect U.S. inventors and the American public.

III. The Policy Ramifications of the Federal Circuit Decision are Contrary to the Purposes of the AIA and Negatively Impact Biotechnological Innovation.

No productive policy is served by permitting the lower court decision to stand. To the contrary, the decision stands in tension with Congress' stated policy goals, including fostering harmonization with international practice[8] and creating more predictability for businesses

8. The patent laws of significant United States trading partners do not bar patents on the basis of secret sales. For

and the public. It also operates inconsistently with the long-standing principles underlying the "on-sale bar," namely this Court's concern that patenting inventions previously on sale will remove existing knowledge from the public. *Pfaff*, 525 U.S. at 64; *Bonito Boats*, 489 U.S. at 141. Yet under the Court of Appeals' decision, a patent that removes no knowledge from the public (because the claimed invention was never available to the public) is nonetheless invalid if the invention is deemed to have been "on sale" in a confidential transaction.

The Federal Circuit thus set up a scenario wherein a particularly problematic category of secret prior art would be preserved and expanded in the amended 35 U.S.C. § 102, thereby denying patents to deserving, and innocent inventors who could not have known of invalidating prior business transactions. This is because the amended prior art provisions at 35 U.S.C. § 102(a) treat all patent applicants the same, regardless of who created such prior art. Thus, if a prior "secret sale" constitutes prior art, it does so against any patent applicant – not just against applicants that were parties to the sale, but also against applicants who independently invented, diligently disclosed their invention in a patent application, and who could not have known of that sale at all. This was never

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example, under European Patent Office law there is no bar for patenting after a confidential disclosure related to commercial use, *e.g.*, a sales agreement. *E.g.*, *Union Carbide Corp. v. Linde A.G.* [1991] T024188 [E.P.O.] Japan has a sale bar, but if the invention is offered for sale in secret, or under a duty of confidentiality, novelty is preserved. Article 29 Japan Patent Office ("JPO"). One skilled in the relevant art must be able to understand the invention as a result of the public sale. JPO Examination Guidelines Part II. Chapter 2. Section 1.5.3(3)(II).

the law before the AIA, but it would be compelled by Respondent's, and Judge O'Malley's interpretation. *See* section I(b), *supra*.

This unfairness is compounded by expanding the scope of such secret prior art to the rest of the world. There is no competing policy support for the regime created by the Federal Circuit's system; only inscrutable uncertainty for businesses and inventors. Smaller innovative businesses that are not vertically integrated and that depend on external investment and product development partnerships, as is typical in biotechnology, are especially impacted.

Small biotechnology companies are responsible for 70% of the global clinical pipeline and 84% of all drug development programs for the more than 7,000 rare diseases that affect one out of five Americans.[9] Many of the more than 2,000 small biotech companies in the United States were founded as university spinoffs to undertake research that is deemed too speculative by larger, established biopharmaceutical companies. A typical small biotech company has fewer than 50 employees, occupies a leased facility, is burning upwards of $10 million per year, and has access to only enough venture capital to finance a few years of operations at most.

But even if initial research results are promising, it takes on average more than ten years of R&D before a

9. David Thomas and Chad Vessel, Emerging Therapeutic Company Investment and Deal Trends, BIO Industry Analysis 2017, available at: https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%202007-2016.pdf

new biotech therapy can be approved by the U.S. Food and Drug Administration.[10] And chances of that happening are slim: the likelihood that a new medicinal molecule will even advance to human testing is less than 1:1000. And the few compounds that do enter human testing empirically have a close to 90% failure rate.[11] Small biotechnology companies typically have neither the funds (the out-of-pocket costs of commercializing a biotech drug exceed $1.3 billion[12]) nor the expertise to conduct human clinical testing (this being the domain of larger biopharmaceutical companies). For these reasons, small biotechnology companies very often need multiple rounds of investment, and depend on business and development partnerships to spread the expense and risk of product development.

Given the need for interactions with potential investors and business partners, small biotechnology companies are far more likely than large companies to engage in pre-commercial disclosures of their inventions. Potential partners and investors of course want sufficient details about a company's research, but are often reluctant to sign confidentiality and non-disclosure agreements early in a relationship. Concern about what can be disclosed

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10. Jorge Mestre-Ferrandiz, Jon Sussex, Adrian Towne, The R&D Cost of a New Medicine, Office Of Health Economics, London 2012, available at https://www.ohe.org/system/files/private/publications/380%20-%20R%26D%20Cost%20NME%20Mestre-Ferrandiz%202012.pdf?download=1.

11. *Id.*

12. Joseph A. DiMasi, Henry G. Grabowski, Ronald W. Hansen, Innovation in the pharmaceutical industry: New estimates of R&D cos s, *Journal of Health Economics*, Volume 47 May 2016, pp. 20-33.

in partnering and investor meetings is common among small biotech companies whose research programs include valuable trade secrets. And filing patent applications first may not always be a reasonable option.

For example, a company's research program may have produced thousands of medicinal molecules, or thousands of therapeutic antibody candidates, but it may at that stage be completely unknown which candidate will be best suited for human testing and should therefore be patented. Proactively filing hundreds of patent applications would be wasteful and unrealistic.[13] Such molecules may be "ready for patenting" within the meaning of patent law, but be far from "ready for patenting" under reasonable business practices. Nor would public policy be served by systematically encouraging the premature patenting of molecules that will, for the most part, turn out to be not commercially viable.

Further business uncertainty arises from the many forms of business transactions under which a development-stage biotech invention might be deemed transferred between businesses for consideration. Small and large companies sometimes contract work out to specialist companies, where medicinal molecules or antibody candidates are made to specification under purchase orders. Development partnerships between

13. Indiscriminate pre-emptive patent filing would tend to suppress pre-patent exploration of an invention to avoid potential "public" disclosure, thus stifling innovation and creating burdens on the patent system. *See* Cotropia, *The Folly of Early Filing in Patent Law*, 61 Hastings L.J. 65 (2009); Karshtedt, *The Riddle of Secret Public Use: A Response to Professor Lemley*, 93 Tex. L. Rev 159 (2015).

companies often take the form of licenses involving upfront payments and the transfer of materials or processes; or sometimes a larger company acquires the smaller company's research program and grants a license of co-development rights back to the small company. Sometimes potential partners are willing to make a preliminary investment in the small company's research program, but demand contingent assignment rights under which the larger company would get to own the program for a predetermined payment if certain future milestones are met. Under the lower court's decision there is a real risk that such typical transactions, even if they are conducted under strict confidentiality, would be deemed to place the invention in the public domain.

No such business uncertainty would be experienced by large pharmaceutical companies that are likely to have the resources to develop their own products without seeking partners. But the decision below impacts innovative businesses of all sizes – large companies would be impacted because their ability to access interesting small-company innovations to feed their product pipelines is diminished. And large companies are typically the ones who spend hundreds of millions, if not billions of dollars to bring a drug to market. Such investment would be put at risk if a confidential transaction involving the candidate drug were to be deemed a "sale" in litigation a decade or more later, after a drug product has been brought to market against all odds. And smaller companies would be impacted more directly, and more harshly, because they depend on partnering and external funding, and are more likely to have to report business transactions publicly, which would greatly increase the risk of unfairly triggering a patent-defeating event. The result below is

especially harsh when a "sale" is deemed to have occurred in a clearly pre-commercial setting, long before it is even clear whether a biotech invention can receive FDA approval and actually be sold to the public, and where the transaction was undertaken to fund the development of the invention.

CONCLUSION

The Federal Circuit's decision is contrary to the AIA and this Court's precedent, is contrary to sound public policy, and should be reversed.

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No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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INTEREST OF AMICI

Amici are professors who teach and write about patent law at schools throughout the United States. We have no personal interest in the outcome of this case, but have a professional interest in seeing that the patent law develops in a clear way that serves its constitutional purpose.[1]

SUMMARY OF ARGUMENT

The key legal question in this case is simple: did Congress mean to sweep away scores of established cases under the 1952 Act even though it reenacted language unchanged since 1870, and in some cases dating from 1790, merely because it added the phrase "or otherwise available to the public" to the list of prior art categories in the new AIA section 102? We think not. We have three primary reasons. First, Petitioner's reading is inconsistent with the language and structure of the AIA. Second, it is inconsistent with Congressional intent in readopting the "on sale" and "public use" language in section 102. Finally, it would sweep away scores of cases decided over two centuries and radically rewrite a host of patent doctrines.

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1. No one other than the undersigned drafted any portion of this brief or contributed any money towards its preparation or filing. The parties have filed blanket consent to amicus briefs.

I. The AIA Did Not Change the Meaning of the Term On Sale by Reenacting It

A. The Terms "Public Use" and "On Sale" Have a Settled Meaning This Court Should Not Disturb

Because the terms "public use" and "on sale" have been in the patent statute since 1836, 5 Stat. 117 (1836), and have consistently been interpreted during that time to extend to secret commercial sales and uses, the relevant question is not simply "what do the terms 'public use' and 'on sale' mean?" but "did Congress intend to change the settled meaning of those terms?" It is a well-established principle of statutory interpretation that when Congress reenacts existing statutory language it is presumed to acquiesce in the way the courts have interpreted that language. *See, e.g.*, *Standard Oil Co. of N.J. v. United States*, 221 U.S. 1, 59 (1911) ("[W]here words are employed in a statute which had at the time a well-known meaning at common law or in the law of this country they are presumed to have been used in that sense . . . ."); *Neder v. United States*, 527 U.S. 1, 21 (1999) ("'[W]here Congress uses terms that have accumulated settled meaning under . . . the common law, [we] must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of these terms.'" (quoting *Nationwide Mut. Ins. Co. v. Darden*, 503 U.S. 318, 322 (1992))); *GPX Int'l Tire Corp. v. United States*, 666 F.3d 732, 739 (Fed. Cir. 2011) (identifying Supreme Court cases that support this principle). Indeed, the Supreme Court applied this principle to the Patent Act as recently as 2011, when it concluded that the phrase "a patent shall be presumed valid" in the 1952 Act required the application of a clear

and convincing evidence standard because courts before 1952 had interpreted the presumption to be rebutted only with clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242, 2246 (2011). So it is reasonable to apply a strong presumption that both "public use" and "on sale" mean the same thing in the AIA as they meant in the 1952 Act (or the Patent Act of 1870, for that matter). "'[I]t is a cardinal rule of statutory construction that, when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it is taken.'" *Air Wis. Airlines Corp. v. Hoeper*, 134 S. Ct. 852, 861–62 (2014) (quoting *FAA v. Cooper*, 132 S. Ct. 1441, 1449 (2012). This Court should ignore that rule only if there is simply no way to make sense of the statute otherwise. As we show in the next section, that is not true of "public use" and "on sale."

B. The District Court's Holding Is Inconsistent with the Language and Structure of the AIA

The purpose of AIA § 102(b) is to provide exceptions to the general rule of AIA § 102(a), the new first-to-file novelty rule. The exceptions are in the form of a grace period. In drafting AIA § 102(b), Congress made "disclosures" (i.e., prior art events) the focus of the grace period. This is important for two reasons. First, "disclosure" means any prior art event – including a "public use" or "on sale" event. Under venerable and voluminous case law, this includes non-informing public uses; use or sale of a machine's output (rendering the machine itself in "public use"); and secret or confidential sales of a patented item. *See* Section III, *infra*.

Under the AIA, all of these prior art events, as traditionally defined, are *disclosures*. To be precise, under the AIA there are two types of disclosures that qualify for the grace period exceptions: (A) the inventor's own (or "first party") disclosures; and (B) third party disclosures. In both § 102(b)(1)(A) and (B), "disclosure" means the same thing: any prior art falling within the categories listed in § 102(a)(1) ("patented, described in a printed publication, or in public use, on sale . . . "). Those terms have been carried over from 1870 intact, and in some cases from the Patent Acts of 1790 and 1836. The meaning of each category naturally incorporates all the well-settled case law interpreting it. Put simply, "disclosure" means "prior art as traditionally defined."

Second, the statute distinguishes between "disclosures" and "public disclosures." The exception in 102(b)(1)(B) says third party disclosures (stated passively, as "the subject matter disclosed," with no limitation on who is doing the disclosing) are also not part of the prior art, if made within one year of filing – and *if preceded by a "public disclosure"* by the inventor. Disclosures, in other words, are specifically defined to be different from *public* disclosures.

AIA § 102(b) is therefore inconsistent with the idea that Congress meant to eliminate all non-public categories of prior art. In particular, the crucial distinction between "disclosures" and "*public* disclosures" in AIA § 102(b)(1) demonstrates that not all prior art events ("disclosures") are public disclosures.[2] It is crystal clear from the text of

2. This is also evident from AIA § 102(b)(2), which defines prior-filed patent applications as "disclosures" and makes the information in them ("the subject matter disclosed") prior art:

AIA § 102 that the term "disclosure" in § 102(b)(1) – the grace period provision – refers to any prior art reference in any of the categories of prior art listed in AIA § 102(a):

> A *disclosure* made 1 year or less before the effective filing date of a claimed invention *shall not be prior art* to the claimed invention under subsection (a)(1) if . . . .

The heading for § 102(a), listing the types of references under the AIA, reads: "Novelty; Prior Art." So "disclosure" encompasses any type of prior art. Therefore "public disclosures" must be a special type of disclosure. Public disclosure can't mean the same thing as "disclosures," as Petitioner would have it. Otherwise, the word "publicly"

> (2) DISCLOSURES APPEARING IN APPLICATIONS AND PATENTS.—A disclosure shall not be prior art to a claimed invention under subsection (a)(2) if—
>
> > (B) the subject matter disclosed had, before such subject matter was effectively filed under subsection (a)(2), been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor . . . .

Note that under traditional principles, these secret disclosures become prior art as of their filing date – but only if they are later published as patent applications or issued patents, i.e., a *nunc pro tunc* effect. The point is, they are defined as "disclosures" as of their filing date, despite being completely secret at that time. This provision thus carries forward a category of backdated prior art mandated in § 102(e) of the 1952 Act, which was itself a codification of this Court's analysis and holding in *Alexander Milburn Co. v. Davis-Bournonville Co.*, 270 U.S. 390 (1926).

in front of the word "disclosed" in the third-party grace period of AIA § 102(b)(1)(B) becomes completely redundant. This conflicts with the well-known canon that all words in a statute are presumed to have meaning, and interpretations that render a word redundant are to be disfavored. *United States v. Alaska*, 521 U.S. 1, 59 (1997) ("The Court will avoid an interpretation of a statute that 'renders some words altogether redundant.'" (*quoting Gustafson v. Alloyd Co.*, 513 U.S. 561, 574 (1995)); *Freytag v. Commissioner*, 501 U.S. 868, 877 (1991) ("Statutory interpretations that "render superfluous other provisions in the same enactment" are strongly disfavored.").

If disclosure is already equivalent to public disclosure, the third party prior art covered in AIA § 102(b)(1)(B) could have been handled much more easily by appending one sentence to AIA § 102(b)(1)(A): After the current text of (b)(1)(A), Congress could have said simply "An inventor's disclosure also eliminates prior art status for subject matter disclosed after the inventor's disclosure." Instead, it provided a completely separate rule for third party disclosures. When we understand "public disclosure" as a subset of prior art "disclosures," this makes sense. For an inventor to remove third-party events from the prior art requires something more than a simple prior disclosure: it requires a public disclosure. The "super" grace period of § 102(b)(1)(B) (i.e., eliminating third party prior art) is "earned" by an act that goes beyond mere prior disclosure by the inventor: it requires a public disclosure. A public disclosure makes information readily available to the public, as opposed to some types of disclosures which do not. The greater benefit of removing third party prior art (as opposed to inventor-own prior art) is deserved only when the inventor makes a greater contribution: a public (more readily accessible) disclosure.

To summarize: There is no escaping the fact that the district court opinion in the *Helsinn* case simply reads the word "public" right out of the statute. In doing so, it renders the language and structure of section 102 nonsensical. That cannot be the right interpretation.

II. The Legislative History Does Not Support a New "Publicness" Requirement

The history of the drafting of the AIA suggests that it did not intend to narrow the universe of prior art to exclude commercial uses and sales that were not disclosed to the public. The original bill introduced in Congress in 2005 would have eliminated the categories of public use and on sale altogether, defining prior art as only things "patented, described in a printed publication, or otherwise publicly known." H.R. 2795, 109th Cong. § 3 (2005). Senator Kyl expressly noted that the purpose of dropping public use and on sale in his bill was to "eliminat[e] confidential sales and other secret activities as grounds for invalidity."[3]

But that language was not the language Congress adopted. During the course of six years of Congressional debate, Congress added the terms "public use" and "on sale" back into the definition of prior art. Indeed, Senator Kyl and two others objected to adding that language because they said it would add secret uses back to the definition of prior art.[4] To limit those terms only to uses

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3. 154 Cong. Rec. 22,631 (2008) (statement of Sen. Jon Kyl). That statement was in reference to a 2008 Senate bill that went back to the original 2005 House language, but which was ultimately not adopted.

4. *See* S. Rep. No. 111-18, at 60 (2009) (supporting removing language from the Patent Reform Act of 2009 relating to patent-forfeiture provisions "that apply only to non-public prior art").

and sales that were publicly known would render that decision a nullity—the statute would have precisely the same effect as if the terms "public use" and "on sale" were excluded altogether. An interpretation of a statute that renders a portion of it a nullity is strongly disfavored.[5] That is particularly true when the terms were specifically added to the bill during the legislative process.

Against the considerable weight of this statutory interpretation, those who claim the AIA changed the settled meaning of "on sale" and "public use" offer only a relatively weak form of legislative history—the statements of individual Senators. The basis of the argument is a "colloquy" on the floor of the Senate the day *after* the Senate had passed the AIA, in which Senator Leahy expressed his view to Senator Hatch that "subsection 102(a) was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States . . . may be deemed patent-defeating prior art."[6] Senator Kyl made similar statements about his interpretation of the statute the day before.[7] This prepackaged "conversation" enabled certain members of Congress to express their view that the established case law should be overruled. But the floor statement of two members of Congress articulating their

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5. *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001).

6. 157 Cong. Rec. 3415 (2011) (statement of Sen. Patrick Leahy). Senator Hatch did not respond to this point, instead turning to different issues. *Id.* at 3415–16. Hal Wegner has called this "*faux* legislative history" because it was created after the fact to explain a bill that had already passed. Harold C. Wegner, The 2011 Patent Law: Law and Practice 138 (4th ed. 2011).

7. 157 Cong. Rec. 3423–24 (2011) (statement of Sen. Jon Kyl).

personal intent, unexpressed in the statute, to overrule existing law should not change settled law. Whatever the merits of legislative history more generally, the statements of individual members of Congress on the floor are particularly weak legislative history because there is no reason to think that they speak for anyone but themselves. *Mims v. Arrow Fin. Servs., LLC*, 132 S. Ct. 740, 752 (2012) ("[T]he views of a single legislator, even a bill's sponsor, are not controlling"); *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 457 (2002) (""Floor statements from two Senators cannot amend the clear and unambiguous language of a statute."); *Patriotic Veterans, Inc. v. Indiana*, 736 F.3d 1041, 1053 (7th Cir. 2013) ("[T]he comments of individual senators do not necessarily reflect Congress's intent in enacting any particular piece of legislation."); *Wis. Educ. Ass'n Council v. Walker*, 705 F.3d 640, 652 (7th Cir. 2013) (stating that a single comment "reveals little of the intent of the legislature as a whole"). That is particularly true here because other members of Congress who supported the AIA, notably Representative Zoe Lofgren, publicly took a different view.[8]

A somewhat stronger form of legislative history lies in the official reports written by the Committee that

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8. 157 Cong. Rec. H4424 (daily ed. June 22, 2011) (statement of Rep. Zoe Lofgren). Representative Lofgren sought to submit an amendment to H.R. 1249 on the floor of the House to clarify that all existing categories of prior art were subsumed in the term "disclosure," but the Rules Committee would not allow the amendment to be presented, so there was no opportunity for Congress to discuss or vote on the question. *H.R. 1249—America Invents Act*, House of Representatives Committee on Rules, http://rules.house.gov/bill/112/hr-1249, *archived at* http://perma.cc/W5S-FTRW.

advanced the legislation to the floor.[9] Those reports, unlike a colloquy, at least purport to speak for the Committee as a whole. Notably, the House Report accompanying the 2007 bill—the one that reintroduced the "public use" and "on sale" language—expresses an intent to adopt the "public use" and "on sale" language "primarily because of how the terms 'in public use' and 'on sale' have been interpreted by the courts." H.R. REP. No. 110-314, at 57 (2007). That—coupled with the fact that the bill was changed to add those terms over the objections of the Senators who wanted to overrule *Metallizing*—suggests that the best reading of that history is that Congress did not deliberately throw out the definitions of "public use" and "on sale" as they have existed for decades, even if a few Senators wished it were otherwise. *See* Mark A. Lemley, *Does Public Use Mean the Same Thing It Did Last Year?*, 93 TEX. L. REV. 1119, 1129-30 (2014) (reaching this conclusion); Daniel Taskalos, Metallizing Engineering*'s Forfeiture Doctrine After the America Invents Act*, 16 STAN. TECH. L. REV. 657, 685–93 (2013) (same).

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9. Courts are generally hesitant about looking at the legislative history of a bill from a prior Congress. But here there is a more compelling case for looking at it because the only report for the enacted AIA states "the bill is a 6-year work in progress" and cites hearings from 2005 to 2010. H.R. REP. No. 112-98, at 57 (2011). That is particularly true where, as here, the final statutory language was settled on in the 2007 term and did not change thereafter. *Compare* H.R. 1908, 110th Cong. (as introduced in House of Representatives, Apr. 18, 2007), *with* 35 U.S.C. § 102(a)(1) (2012).

III. The Addition of "Otherwise Available to the Public" Should Not Change This Result

A. Petitioner's Approach Would Radically Rewrite the Law of Prior Art

Petitioner's reading of AIA § 102(a) will cause all manner of mischief. As noted above, it eliminates the disclosure/public disclosure distinction that is so central to AIA § 102(b)(1). It also attributes a quite radical intent and effect to the new prior art provision in the AIA: it would sweep away scores of cases, accumulated over two centuries, defining in great detail each of the specific categories of prior art listed in AIA § 102(a). Opinions by giants in the patent field, from Joseph Story to Learned Hand to Giles Rich – gone, by virtue of one added word in the new statute. With no legislative hearings on this radical move, despite Congress's decision to reenact the very language that has been in the Patent Act for a century without alteration, without even any legislative history describing why the definition of prior art is being changed so radically, we are to assume that Congress just decided on a major sea change in this very old and very much relied-upon body of law, and implemented it by reenacting the very language that gave rise to that body of law? That seems highly unlikely.

In a vacuum, Petitioner's reading of "or otherwise available to the public" is plausible. But to see why it is so disruptive, it is helpful to lay out the details of this interpretation. Under the district court's reading, the statute as written is taken to mean, in effect:

> (1) the claimed invention was [a] patented [in a manner available to the public], [b] described in a printed publication [in a manner available to the public] , or [c] in public use [in a manner available to the public], [d] on sale [in a manner available to the public], or [e] otherwise available to the public. . . .

35 USC § 102(a)(1) (with insertions and annotations).

How much change would this reading work in existing caselaw? We consider this by prior art reference types, annotated [a] through [e]. Patents and printed publications ([a] and [b]) would not change much if at all. A patent is, by its nature, open to the public; the word "patent" derives from the Latin *patere* meaning "open or lying open." And under a long line of cases, a "printed publication" is defined as a reference that is accessible to the public. *In re Klopfenstein*, 380 F.3d 1345, 1348 (Fed. Cir. 2004) ("[T]he key inquiry is whether or not a reference has been made 'publicly accessible.'"). Perhaps the advent of the new statute would cause courts to revisit "borderline" cases, such as *In re Hall*, 781 F.2d 897 (Fed. Cir. 1986), in which a single copy of a graduate thesis in one library in Germany was ruled a "printed publication." But in general it is quite plausible that the law under the 1952 Act would for the most part carry forward cleanly under the district court's reading of AIA § 102(a).

Not so for prior art references [c] and [d]: 'public use' and 'on sale' prior art. The district court reading of AIA § 102(a) would result in the overturning of a huge body of case law for both types of references. In particular, the AIA would be found to have impliedly overruled cases in

three major areas: (1) "noninforming public use" cases, where an invention is used in public but in a way that is not ascertainable by (and hence arguably not "available to") the public; (2) "output of a patented machine or process" cases, such as ***Metallizing Engineering***; and (3) secret, confidential, and nonpublic sales transactions, which under the on sale cases cover the vast majority of on sale events. In each of these cases, notwithstanding the suggestion of the United States to the contrary, the law has always treated "secret" sales and uses as prior art.[10]

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10. It might be tempting to conclude that the word "disclosure" in AIA § 102(b) implies a degree of widespread access, but this is not correct. A disclosure can be limited to a very few people yet still be a disclosure. We know this, for example, because of the widespread use of "nondisclosure agreements" in trade secret law, which prohibit unauthorized transfers of information to third parties no matter how secret or limited. See generally Robert P. Merges, ***Priority and Novelty Under the AIA***, 27 BERKELEY TECH. L.J. 1023, 1036 (2012) ("There is room . . . for the idea of a 'secret disclosure'—a disclosure that goes beyond absolute nondisclosure but not nearly all the way to wide-open and free dissemination.").

Indeed, the term "disclosure" has long been understood by patent lawyers, Congress, and the courts as synonymous with "prior art references." Section 103 of the 1952 Patent Act said that "[a] patent may not be obtained, though the invention is not identically ***disclosed or described as set forth in section 102 of this title . . .***" 35 U.S.C. §103(a) (2000). That statute uses the term "disclosed" to refer to everything that was prior art under the public use and on sale prongs in the 1952 Act, including non-public art. Court opinions similarly use the term "disclosure" expansively to refer to all prior art. Thus, in ***OddzOn Products v. Just Toys***, the court addressed whether a § 102(f) confidential disclosure could also be used as prior art under § 103. 122 F.3d 1396 (Fed. Cir. 1997). OddzOn Products argued that "because these disclosures are not known to the public, they do not possess the usual hallmark

There are many noninforming public use cases. The classic is *Egbert v. Lippmann*, 104 U.S. 333 (1881). The inventor's corset stay, worn inside his fiancee's well-covered corset (it was 1881; pre-Lady Gaga) was used without any express restriction for over 10 years – a public use, according to the Court. Modern cases such as *Lough v. Brunswick Corp.*, 86 F.3d 1113 (Fed. Cir. 1996) (involving the unrestricted use of inboard-outboard boat engines containing an unobservable internal engine seal) follow *Egbert*. All these cases are arguably swept away by the district court's interpretation. It is impossible to say how many cases would be eliminated, though the main holding of *Egbert* has, according to Westlaw, been cited 45 times for the proposition that it was a public use.

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of prior art, which is that they provide actual or constructive public knowledge." *Id.* at 1401. This Court rejected that argument, concluding that derivation under old (pre-AIA) section § 102(f) was prior art that could be used for an obviousness inquiry. *Id.* at 1401-02. Notably, both the court and the party arguing against prior art status for secret information used the term "disclosures" to refer to that secret prior art. That usage by both courts and litigants is consistent with the idea that "disclosures" in patent law has traditionally meant "anything that qualifies as a prior art reference," not a particular level of publicness. Other cases use the term consistently. *See, e.g., Hazeltine Research, Inc. v. Brenner*, 382 U.S. 252, 253, 256 (1965) (finding a filed patent application to be prior art for § 103 purposes even though "its disclosures were secret and not known to the public"). Thus, in *Conmar Prods. Corp. v. Universal Slide Fastener Co.*, 172 F.2d 150 (2d Cir. 1949), Judge Hand referred to a putative piece of prior art as "Poux's disclosure" even though it was not in fact public as of the priority date. *Id.* at 152–53. Similarly, *White Cap Co. v. Owens-Ill. Glass Co.*, 203 F.2d 694 (6th Cir. 1953), speaks of a rejected patent application that never became public, and therefore did not qualify as prior art, as the "Armstrong disclosure." *Id.* at 696.

The upshot is the same regardless: a well-settled rule of law, established for over 125 years, would be swept away. Until the contours of the new "[c] public use [in a manner available to the public]" type of prior art are established, uncertainty would reign.

A second category of public use cases would be wiped away by the district court holding: those where the output of a patented machine is used publicly. The classic here is *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946). In *Metallizing Engineering*, Judge Learned Hand identified the crucial policy behind a strict reading of the public use bar: "[I]f [an inventor] goes beyond that period of probation, he forfeits his right regardless of how little the public may have learned about the invention . . . ." Id., at 520. Again, it is difficult to say with precision how much precedent Petitioner's approach erases; but the main holding in *Metallizing* has been cited in 30 cases and explicitly adopted in numerous patent cases. *See, e.g., Kinzebaw v. Deere & Co.*, 741 F.2d 383, 390 (Fed. Cir. 1984); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983); *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147 (Fed. Cir. 1983); *see also Moore v. United States*, 194 U.S.P.Q. 423, 428, 1977 WL 22793, at *5–6 (Ct. Cl. 1977) (endorsing *Metallizing*); 2 DONALD S. CHISUM, CHISUM ON PATENTS § 6.02[5][b], at 6–61 (2014) ("[I]t is now well established that commercial exploitation by the inventor of a machine or process constitutes a public use even though the machine or process is held secret.").

A final category of cases the district court sweeps away are "on sale" cases where the sale or offer is secret, confidential or non-public. Because public availability has

never been a requirement in on sale cases, it is difficult to say with precision how many cases are affected. It is quite clear, however, that the confidential nature of a sale under the 1952 Act has always been irrelevant in determining whether the on sale bar applies. *E.g.*, *Pfaff v. Wells Elec., Inc.*, 525 U.S. 55 (1998) (nowhere mentioning whether the purchase order that constituted the on sale event was ever made public; presumably it was not); *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2002) ("the on-sale bar would apply even if a patentee's commercial activities took place in secret."); *Buildex Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1464 (Fed. Cir. 1988) (holding that a firm offer sent to prospective purchaser was an "on sale" event, despite the fact that the offer was marked "confidential"). The district court here explicitly required that a sale be public to be prior art, not only ignoring that history but ignoring the plain language of the term "on sale" itself, which requires no such publication.

In the cases under [c] and [d], public use and on sale prior art, the lack of any "publicness" requirement under the 1952 Act makes sense in light of the original policy rationale for the statutory bars. Going all the way back to the foundational case of *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829) (Story, J.), the rationale for the statutory bars has been to prevent the extension of the patent monopoly. Indeed, in the *Pennock* case itself, Justice Story specifically mentioned the *lack* of comprehensive public disclosure during the pre-filing exploitation of an invention:

> If an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention; if he should, for a long period

> of years, retain the monopoly, and make and sell his invention publicly; and thus gather the whole profits of it, relying upon his superior skill and knowledge of the structure; and then, and then only, when the danger of competition should force him to procure the exclusive right, he should be allowed to take out a patent, and thus exclude the public from any further use, than what should be derived under it, during his fourteen years; it would materially retard the progress of science and the useful arts; and give a premium to those who should be least prompt to communicate their discoveries.

27 U.S. at 10. Requiring that sales be public to be prior art would permit just the sort of mischief *Pennock* was intended to prevent – patent owners who commercialize their inventions for years without risk of losing the ability to patent the technology years or even decades later. The government's position would be even worse; so long as the public as a whole couldn't obtain the products, companies that sold specialized products to restricted audiences could do so indefinitely without giving up their right to file a patent. That is the opposite of what the statutory bars were intended to do.

Further, were this Court to revisit the public aspect of "on sale" despite the reenactment of that term in the AIA, who is to say other courts would not also revisit the detailed case law on what constitutes an offer for sale[11] or the rule that the on sale bar is triggered when

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11. *See, e.g., Gemmy Indus. Corp. v. Chrisha Creations Ltd.*, 452 F.3d 1353, 1359–60 (Fed. Cir. 2006) (holding that statement

the invention is ready for patenting, even if it hasn't yet been built?[12] None of those rules flows inexorably from the meaning of the words "on sale," and if the "on sale" of the AIA is different than the "on sale" of the 1952 Act, all those interpretations are open to question. So too are the obviousness cases that depend on these categories of prior art.

Nor does the uncertainty end there. Section 102 is full of terms that have taken on a judicial gloss that alters what the terms might mean to the untutored. A "printed publication" does not by its terms include a website or a PowerPoint presentation, but courts have interpreted both to fit within the meaning of the term.[13] If reenacting old statutory language is an invitation to revisit the meaning of that language, we will lose all the benefit of more than a century of case law interpreting those terms. We will have to start over, with no guarantee that the settled meaning

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by patentee's president did not establish date of first sale for purposes of on sale bar); *In re Kollar*, 286 F.3d 1326, 1333 (Fed. Cir. 2002) (holding that license agreement was not a "sale"); *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1048 (Fed. Cir. 2001) (holding that "[o]nly an offer which rises to the level of a commercial offer for sale . . . constitutes an offer for sale under" the on sale bar).

12. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67–68 (1998).

13. *E.g.*, *Suffolk Techs., LLC v. AOL Inc.*, 752 F.3d 1358, 1364–65 (Fed. Cir. 2014) (holding that unindexed Usenet newsgroup posting is a printed publication); *Voter Verified, Inc. v. Premier Election Solutions, Inc.*, 698 F.3d 1374, 1379–80 (Fed. Cir. 2012) (holding that unindexed web page is a printed publication); *In re Klopfenstein*, 380 F.3d 1345, 1352 (Fed. Cir. 2004) (holding that a PowerPoint presentation and posters presented temporarily at a conference are a printed publication).

of these old terms will carry over into the new statute. And because it will be years before patents issue and are regularly litigated under the AIA, it will be a very long time before we can know for sure whether the scope of prior art is the same as it was before the AIA.

The problems don't even end there. The definition of prior art includes not only terms like "public use" and "printed publication" but also many judicially-created doctrines that refine the scope of prior art. The inherency doctrine, for example, like the *Metallizing* rule, is not articulated expressly in either the old or new statute. *Tilghman v. Proctor*, 102 U.S. 707 (1880). If the reenactment of the term "public use" opens the door to revisiting *Metallizing*, it also opens the door to revisiting inherent prior art, which by definition isn't "available to the public." The same is true of the experimental use exception to the on sale and public use bars. That exception doesn't exist in the statute; it was created by the Court in the nineteenth century. *Elizabeth v. Pavement Co.*, 97 U.S. 126, 137 (1877). But if the touchstone for the new meanings of public use and on sale is public availability, there is no reason to think those new terms should include an unarticulated exception for uses and sales that are public but nonetheless experimental.[14] Similarly, the rule that prior art must be enabling exists nowhere in the statute;[15] courts would be free to revisit that requirement and conclude that a public description of the invention was prior art whether or not it was enabling, so long as the

14. For a discussion of whether and under what circumstances experimental use survives the AIA, see Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. Rev. 1171 (2016).

15. *In re Hafner*, 410 F.2d 1403, 1405 (C.C.P.A. 1969).

publication was available to the public. And litigants might also question the doctrine of double patenting,[16] which is similarly not articulated anywhere in § 102.

Patent law would be much better served by leaving existing precedent interpreting unchanged statutory terms in place. The AIA creates enough uncertainty with a variety of new language. Concluding, as the district court did here, that we must revisit all our old decisions even where Congress chose to reenact old language would doom us all to decades of uncertainty as to the scope of prior art.

B. So What *Does* "Otherwise Available to the Public" Mean?

It is most important to reverse the holding that "otherwise available to the public" implies a new publicness requirement for all categories of prior art. But this leaves the question of the proper interpretation of this phrase.

The best understanding is that it is a residual category meant to capture all publicly accessible prior art that does not fit into one of the other enumerated categories. For example, this residual category would cover a future technology which permits widespread public access but which may not be a "publication" or public "use." It might cover a situation where someone makes available a digital file that, when downloaded, prompts a 3-D printer to print out a certain design. The file might not itself be a "publication"; and it may not be "used" to print a product

16. *In re Kaplan*, 789 F.2d 1574, 1578–79 (Fed. Cir. 1986); *In re* Vogel, 422 F.2d 438, 441–42 (C.C.P.A. 1970).

right away. But mere public availability would make it prior art as of the date it is first made available.[17]

This reading is consistent with Judge O'Malley's concurrence below. Terminal limiting clauses or phrases ordinarily should be read to modify only the noun or phrase that immediately precedes them. *See Barnhart v. Thomas*, 540 U.S. 20, 26 (2003). "This is especially true where, as here, the phrase at issue is separated from the preceding phrases with a comma, followed by use of the word "or," implying that what follows the comma is something different from and independent of the preceding concepts. This doctrine implies that 'to the public' limits only 'otherwise available.' In other words, "otherwise available to the public" is a catchall provision that encompasses means by which the claimed invention can be disclosed to the public that are not otherwise accounted for in § 102(a)." *Helsinn v. Teva*, __ F.Appx. __ (Fed. Cir. 2018) (O'Malley, J., concurring in denial of en banc rehearing).

In any event, even if it is not completely clear what the residual category covers, it is imperative not to read a new "publicness" element into preexisting prior art categories. To do so would be wildly out of step with the tradition of continuity in patent law and would cause

17. Notably, cases under the 1952 Act already speak of prior art as being "reasonably accessible to the public." *Hall*, *supra*. But that is a term of art that does not exclude from the definition art either nominally accessible to the public but practically unlikely to be found or art that is the basis of internal commercial use for more than a year. In that context, adopting the language "accessible to the public" would seem to reflect Congressional intent to maintain that definition, not contradict it.

extreme uncertainty in the world of patent law. It is unnecessary and unwise, in light of the overall structure of AIA § 102. Given that the district court's reading of the phrase "or otherwise available to the public" is not the only plausible one, and given that the district court chose the interpretation that is at odds with the rest of the statute, the legislative history, and principles of statutory interpretation, as well having far more disruptive and radical effects, the best conclusion is that "public use" and "on sale" mean the same things they have always meant.

CONCLUSION

The Federal Circuit's interpretation of "on sale" should be affirmed. The term should be construed to have the same meaning it had in the 1952 Patent Act. The language, structure and logic of AIA § 102 dictate this result, and it would preserve intact case law (and expectations based on it) developed over a very long period of time.

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No. 17-1229

In the

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* HOUSTON INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

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INTEREST OF *AMICUS CURIAE*

The Houston Intellectual Property Law Association ("HIPLA") is an association of hundreds of lawyers and other professionals who predominately work in or near Houston, Texas (*see generally* www.hipla.org).[1] The practice of most of the HIPLA membership relates in substantial part to the field of intellectual property law. Founded in 1961, HIPLA is one of the largest associations of intellectual property practitioners in the United States. HIPLA represents the interests of its members and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. HIPLA has no stake in any of the parties to this litigation or in the outcome of this litigation.

HIPLA believes this amicus brief will assist the Court in deciding this important case involving U.S. patent law. HIPLA takes no position as to the merits of the case before the Court. HIPLA respectfully wishes to draw the Court's attention to some of the

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

Court's applicable precedent, underlying policy issues, and the potential impact of its decision.

SUMMARY OF THE ARGUMENT

The Federal Circuit held below that, notwithstanding every indication that Congress intended to require "public availability" for prior art under § 102(a) of the Patent Act, secret sales and offers for sale could render the invention to be "on sale."

Leading up to the enactment of the Leahy-Smith America Invents Act (AIA), the on-sale bar had long been the subject of criticism regarding its patent-barring reach over secret sales of a claimed invention that result in no disclosure of the invention to the public. Congress intended to and did eliminate this "secret" prior art as part of the AIA—arguably the most comprehensive reform of the law of patentability in U.S. history. In doing so, Congress sought to balance the rights of the patentee in obtaining patent protection with the rights of the public to inventions that have entered the public domain. On one hand, it expanded the scope of the on-sale bar to include foreign sales, while on the other, it excluded sales that did not disclose the invention to the public. The lynchpin to the balance

that Congress sought to achieve lies in the addition of a public availability qualifier to patent-barring sales, a requirement that is abundantly clear both from the text of the statute and its lengthy legislative history.

The Federal Circuit's holding contravenes the plain text of the statute and ignores the expressed intent of Congress. The court's interpretation largely stands alone, conflicting with the understanding of the United States government, the Patent and Trademark Office (Patent Office), and the patent bar over the past five years. It expands radically the scope of patent-invalidating prior art, while frustrating Congress's attempt to harmonize U.S. patent laws with those of the rest of the developed world.

Allowing the on-sale bar to extend to secret sales furthers no policy goals and instead incentivizes inventors to maintain secrecy over their intellectual property, thereby preventing disclosure of inventions into the public domain and hindering the progress of science and the useful arts.

ARGUMENT

I. Under the AIA, "on sale" requires public availability to bar a patent.

Both the AIA and the preceding 1952 Patent Act set forth conditions for patentability. One of these conditions is novelty—a person is not entitled to a patent for an invention that is not new. Before the AIA, for instance, a patent applicant was not entitled to a patent if, more than one year before the date of the application for patent in the United States, the invention was "patented or described in a printed publication in this or a foreign country" or if the invention was "in public use or on sale in this country." 35 U.S.C. § 102(b) (2006). That is, the pre-AIA statute defined two broad categories of patent-barring prior art—documents (i.e., patents and printed publications) and activities (i.e., public use and on sale). These two categories had different geographic scope. While documents from any country could be used to bar a patent under pre-AIA § 102(b), the public-use and on-sale activities would only be patent-barring if performed in the United States.

The AIA moved the United States from a first-to-invent to a first-inventor-to-file patenting system and included significant changes to § 102. Like the previous statute, the new § 102 also identifies

documents and activities that can bar a patent. The new statute, however, removes the geographic restriction from the public-use and on-sale activities. That is, while public-use or on-sale activities could bar a patent under pre-AIA § 102(b) only if these activities were in the United States, the new § 102 allows such activities to bar a patent regardless of where the activities were performed.

With this geographic restriction removed, Congress consolidated the patent-barring documents and activities enumerated in pre-AIA § 102(b) into the new § 102. But Congress also added a catch-all provision following the public-use and on-sale activities:

> (a) NOVELTY; PRIOR ART.—A person shall be entitled to a patent unless—
>
> (1) the claimed invention was
>
> patented,
>
> described in a printed publication, or
>
> in public use, on sale, or *otherwise available to the public*
>
> before the effective filing date of the claimed invention[.]

35 U.S.C. § 102(a)(1) (italics and formatting added).

The inclusion of the catch-all phrase "*otherwise* available to the public" (emphasis added) informs

the meaning of the preceding elements "in public use" and "on sale." *See, e.g., Third Nat'l Bank in Nashville v. Impac Ltd., Inc.*, 432 U.S. 312, 322 (1977) ("It is a familiar principle of statutory construction that words grouped in a list should be given related meaning."); *see also id.* at 322, n.16 ("'One hardly need rely on such Latin phrases as *ejusdem generis* and *noscitur a sociis* to reach this obvious conclusion.'") (quoting *United States v. Feola*, 420 U.S. 671, 708 (1975) (Stewart, J., dissenting)).

The adverb "otherwise" means "in a different way or manner." MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 879 (11th ed. 2012). Consequently, § 102(a)(1) bars a patent if the claimed invention was in public use, on sale, or available to the public in a *different* way or manner—that is, in a way or manner that is different than being available to the public through sale or use of the claimed invention. Read in context, the plain language of the statute requires public disclosure of the claimed invention to bar a patent. The decision below contravenes this plain meaning and is in error.

II. The Federal Circuit's decision undermines the balance that Congress achieved through the AIA.

As Judge O'Malley acknowledged in her concurring opinion at the rehearing stage, the chief criticism of allowing the on-sale bar to cover secret sales is that, because such sales do not place the invention in the public domain, allowing a patent on the invention after such a sale does not remove the invention from the public domain. Pet. App. 12a–13a.[2] In fact, the pre-AIA rule has been the subject of such criticism for decades leading up to the enactment of the AIA.[3]

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[2] Judge O'Malley even questioned whether it was fair to consider distribution agreements as offers for sale within the scope of the on-sale bar. Pet. App. 15a.

[3] *See, e.g.*, Dmitry Karshtedt, *Did Learned Hand Get It Wrong? The Questionable Patent Forfeiture Rule of Metallizing Engineering*, 57 Vill. L. Rev. 261, 326 (2012) (noting that secret inventions are never in the public domain); Toshiko Takenaka, *Rethinking the United States First-To-Invent Principle from a Comparative Law Perspective: A Proposal to Restructure § 102 Novelty and Priority Provisions*, 39 Hous. L. Rev. 621, 634-36 (2002) (explaining that the "inclusion of secret commercial use within the meaning of 'public use or on sale'" pre-AIA provisions has "introduce[d] a significant uncertainty in U.S. patent validity"); Iftikhar Ahmed, *What They Don't Know Shouldn't Hurt You: Adding A Public Knowledge Prong to the On-Sale Bar Helps Provide Certainty to Inventors and Competitors Alike*, 45 Hous. L. Rev. 153, 181 (2008) (proposing that the on-sale inquiry focus on the amount of public

Yet, Judge O'Malley reasoned that in light of the fact that Congress chose not to modify the term "on sale," as it had previously appeared in § 102(b), Congress simply did not intend to alter the on-sale bar. Pet. App. 9a–10a (stating that absent a redefinition of "on sale" by Congress or the Supreme Court, the court would continue to apply years of pre-AIA case law regarding invalidating offers for sale).

Quite the contrary, the AIA represented perhaps the most comprehensive patent law reform in U.S. history.[4] The drafting history, which spans a period of six years, demonstrates that a public-availability requirement was always part of Congress's definition of prior art. *See* Pet. Br., at 25–26. In amending the on-sale bar, Congress sought to balance the rights of the patentee to work toward

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disclosure emanating from the sale); Timothy R. Holbrook, *The More Things Change, the More They Stay the Same: Implications of Pfaff v. Wells Electronics, Inc. and the Quest for Predictability in the On-Sale Bar*, 15 Berkeley Tech. L.J. 933, 991 (2000) (suggesting that the information surrounding any offer for sale should serve as prior art); Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 450 n.97 (2012).

[4] *See* Robert A. Armitage. *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1, 4 (2012) ("In a nutshell, the AIA completes a 30-year journey to remake, in their entirety, each of the foundational assumptions underlying the operation of the U.S. patent system.").

commercializing her invention with the rights of the public in an invention that was already in the public domain.[5]

A. Congress expanded the rights of the public by extending the territorial reach of the on-sale bar.

As noted above, the pre-AIA § 102 excused sales and offers for sale of the invention made outside of the United States from triggering the on-sale bar. 35 U.S.C. § 102(b) (2006) ("invention was . . . on sale *in this country*"). The territorial limitation unfairly benefitted foreign inventors, who were more likely to conduct business abroad, over domestic inventors. Taking into account the public-availability qualifier imposed by the amended on-sale bar, Congress eliminated the geographic restriction on this definition of prior art.[6] Undoubtedly, with the convergence of technology, U.S. inventors today regularly do business with foreign partners and the territorial restriction of the 1952 statute seems antiquated.

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[5] The fact that Congress chose not to modify the term "on sale" directly is of no moment given that the amended statute includes other unmodified terms, *e.g.*, "prior art," that clearly carry a different meaning under the amended law.

[6] *See* 157 Cong. Rec. S1371 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl).

The AIA further amended the statute to treat "on-sale" activity the same as all other prior art. *See* 35 U.S.C. § 102(a)(1). Because of the addition of a public-availability requirement to the amended on-sale bar, it becomes unnecessary to determine whether the patent-barring sale is attributable to a specific patent applicant.

Moreover, by implementing a first-inventor-to-file system, the AIA greatly diminished the concerns of allowing inventors an extension of a statutorily limited patent term. Documenting the dates of conception and reduction to practice of an invention no longer provides protection as to patentability of their inventions. An inventor who delays filing for a patent simply risks losing it entirely to another inventor who files first. Inventors are therefore incentivized to promptly seek patents on inventions. The AIA therefore brought some uniformity to the application of the on-sale bar, thereby providing certainty to the public in cases where a sale resulting in public disclosure of the invention does occur.

B. Congress balanced the rights of the patentee by restricting the types of sales that would trigger the bar.

The AIA balanced the expanded scope of the amended on-sale bar by providing certain

protections to inventors who diligently seek patent protection. First, each of Congress's amendments to the scope of the on-sale bar can only be read in view of a public-availability requirement. A radical expansion of the scope of the amended statutory bar to reach secret sales anywhere in the world makes no sense.[7]

Second, the AIA amended 35 U.S.C. § 119 to allow foreign filings to stop the "on-sale" clock thereby eliminating the need for a U.S. filing where the invention was potentially on sale.[8]

The Federal Circuit's decision undermines the balance that Congress sought to achieve by vastly expanding the scope of the pre-AIA on-sale bar. The goal of the on-sale bar is to prohibit delinquent patenting from withdrawing inventions that have already been placed into the public domain through

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[7] *See, e.g.*, Armitage, 40 AIPLA Q.J. at 55, n.206 (recounting legislative history and explaining that reading § 102(a) as covering secret sales would be truly absurd); Matal, 21 Fed. Circuit B.J. at 472; Timothy R. Holbrook, *Territoriality and Tangibility After Transocean*, 61 Emory L.J. 1087, 1114 (2012) (a rule that allows secret foreign offers to bar patentability "could create a broad swath of prior art that is essentially unknowable to parties in the United States.").

[8] *See* 35 U.S.C. § 119(a) (deleting the exception that "no patent shall be granted on any application for patent for an invention which had been . . . on sale in this country more than one year prior to such filing").

commercialization. Expanding the bar to reach secret sales does nothing to advance that goal but instead deters inventors from seeking patent protection.

III. The Federal Circuit's decision jeopardizes many patents and is detrimental to innovation across many industries.

Ever since the AIA was enacted on September 16, 2011, there has been near consensus among the patent bar and the Patent Office that the revised on-sale bar provisions of the AIA do in fact overturn the concept of secret-sale-based prior art.[9]

A. The Federal Circuit's decision eviscerates the public's reliance on the USPTO's interpretation and the shared understanding of the AIA within the patent bar.

Shortly after the enactment of the AIA, the Patent Office issued guidelines for examining patent applications filed after the effective date of the AIA, March 16, 2013. *See* Examination Guidelines for Implementing the First Inventor to File Provisions

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[9] Armitage, 40 AIPLA Q.J. at 54 ("There is abundant ground for confidence that the clarity of the new statutory language will not be negated by the courts, and that the new law will be followed as written.").

of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11,059 (Feb. 14, 2013). Contrasting the pre-AIA law which "include[ed] commercial activity even if the activity is secret," the guidelines told examiners that the amended § 102 does not cover secret sales or offers for sale. *Id.* at 11,075. The guidelines specifically call out commercial activities "among individuals having an obligation of confidentiality to the inventor" as being excluded from the scope of the amended law. *Id.*; *see also* Patent Office's Manual of Patent Examining Procedure § 2152.02(d) (9th ed. 2014) (mimicking the instructions from Examination Guidelines). The patent community across the country has generally agreed with the Patent Office's understanding of the on-sale bar under the AIA.[10] More recently, the government has supported this interpretation in amicus briefs filed with the Federal Circuit. *See* Brief of United States as Amicus Curiae, pp. 4–5, *Helsinn Healthcare S.A.*

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[10] *See, e.g.*, Dennis Crouch, *Did the AIA Eliminate Secret Prior Art?*, Patently-O (Oct. 10, 2012), at http://www.patentlyo.com/patent/2012/10/did-the-aia-eliminate-secret-prior-art.html (discussing major patent law associations, including the AIPLA, the ABA, and the IPO, have taken the position that the AIA statute does in fact overturn the concept of forfeiture); Joseph A. Lingenfelter, *Putting the "Public" Back in "Public Use" Interpreting the 2011 Leahy-Smith America Invents Act*, 31 Ga. St. U. L. Rev. 867, 889 (2015) (noting that many patent attorneys and patent law associations agree with the Patent Office's interpretation of the AIA).

v. Teva Pharms. USA, Inc., Nos. 2016-1284, 2016-1787, 2018 WL 1583031 (Fed. Cir. Jan. 16, 2018) (brief filed May 2, 2016); Brief of United States as Amicus Curiae, pp. 15–17, *The Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) (en banc) (brief filed March 2, 2016).

Over the past five years, millions of patent applications have been examined under the Patent Office's guidelines.[11] Inventors have likely entered into non-public commercial agreements in reliance on the Patent Office's examining guidelines allowing them to do so without triggering the on-sale clock. But given the Federal Circuit's contrary interpretation of the statute, these extensive patent rights are now at risk.

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[11] *See* USPTO Performance and Accountability Report FY 2017, at 168, 171, at https://www.uspto.gov/sites/default/files/documents/USPTOFY17PAR.pdf; *see also*, Dennis Crouch, *Utility and Design Patents – Up Again for 2017*, Patently-O (Dec. 26, 2017), at https://patentlyo.com/patent/2017/12/utility-design-patents.html (noting that the patent office has issued record numbers of patents over the last three years).

B. The Federal Circuit's decision if affirmed would have a huge impact across a wide spectrum of industries and is especially detrimental to solo inventors and small companies.

The Federal Circuit's decision makes it difficult for small businesses across all industries to commercialize innovations that they intended to seek patent protection for. This is particularly true in the pharmaceutical industry given the cost of developing a new drug.[12] This very case exemplifies how a relatively small pharmaceutical company, faced with huge costs of obtaining approval for a drug product, is typically required to enter into purchase agreements with business partners to front the costs of clinical trials and other expenses. *See* Pet. Br. at 8–9. The process to obtain approval of a new drug from the Food and Drug Administration

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[12] While estimates vary, two different studies put the number between $648 million and $2.6 billion. *See* Vinay Prasad et al., *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, JAMA Internal Med. 1569–1575 (Nov. 2017), *available at* https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2653012 (finding the median cost of developing a single cancer drug to be $648.0 million); Aaron E. Carroll, *$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions*, The New York Times (Nov. 18, 2014) (reporting on an estimate by The Tufts Center for the Study of Drug Development).

(FDA) is lengthy and expensive.[13] And while the Petitioner in this case managed to get through the preclinical research as well as the initial phases of clinical trials before seeking out a business partner, other pharmaceutical companies may need to seek out such partnerships at earlier stages of the FDA approval process, significantly lengthening the period between when an agreement is entered into and the time when the company decides to seek patent protection for the drug.[14] In contrast, larger pharmaceutical companies could possibly accomplish the same result in-house without the need for such third-party agreements and without triggering the on-sale bar.

Should the Federal Circuit's decision stand, pharmaceutical companies that relied on the Patent Office's understanding of the statute in delaying their patent filings could lose their ability to protect their intellectual property. Going forward, companies would be forced to avoid any activities that might trigger the on-sale bar even if those activities do not make the claimed invention publicly

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[13] *See* U.S. Food & Drug Administration, *Learn About Drug and Device Approvals*, at https://www.fda.gov/ForPatients/Approvals/default.htm.

[14] *See* FDAReview.org, A Project of the Independent Institute, *The Drug Development and Approval Process*, at http://www.fdareview.org/03_drug_development.php (listing potential timeframes for each stage).

available, thereby impairing a company's ability to raise revenue to support pharmaceutical research. Without partnerships with other companies or venture capital funding sources, smaller companies would be unable to conduct meaningful drug development. In this case, for example, it is possible that Helsinn's drug, which improves cancer patients' health and quality of life, would have never seen the light of day.

On the flip side, when companies do enter into revenue-generating agreements, even those in which, as here, there is no public disclosure of the invention, they would be forced to seek patent protection at early stages of clinical research resulting in premature disclosure of the inventions that would hardly be beneficial to the company or the public.

The Federal Circuit's decision also adversely impacts the software development world, where global collaboration on projects is the norm these days.[15] Today's complex software may comprise many components developed not just at different

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[15] *See, e.g.*, Mathias Strasser, *A New Paradigm in Intellectual Property Law? The Case Against Open Sources*, 2001 Stan. Tech. L. Rev. 4, 46 (2001) (discussing the Patent Office's difficulty in examining software patents owing to the fact that software development is a global and fast-paced process).

companies but in different countries. The Federal Circuit's decision likely reaches licensing agreements between parties executed during the development of such software. Especially in the context of enterprise software, where licensing agreements typically include non-disclosure obligations, software inventions could be "on sale" without any public disclosure of the invention.

The Federal Circuit's reading of the on-sale bar as applying to sales lacking any public disclosure also fails to recognize the new paradigm for software development and sale. In today's "app-based" world, a software vendor may sell an initial version of software to its users, but may decide to "release" features and improvements at a later time through access controls implemented on a server.[16] That is, software to implement a desired functionality may already be available within the software on a customer's device but may only be enabled at a later time of the software vendor's choosing. This practice has become common in cases where a feature may not be ready for release, may require different hardware parameters, or may depend on third party

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[16] *See* Matthew Fagan, *Secret Software Sales*, Patently-O (June 15, 2017), at https://patentlyo.com/patent/2017/06/guest-secret-software.html (discussing potential impact of the Federal Circuit's decision on the modern-day software release approaches).

software functionality that may be unavailable when the software is first "sold" to the user.[17] Under the Federal Circuit's interpretation of the AIA, it is possible that the earlier sale date would trigger the bar even though the "sale" was secret and resulted in no public disclosure.

Continued uncertainty surrounding patent eligibility has significantly discouraged inventors in the software industry from seeking patent protection for their innovations. Industry observers report that software inventors these days look to trade secrets as a more effective means of protecting their intellectual property.[18] Diminished software patenting results in a reduction in information sharing and cooperation, as well as a negative effect on investment in research and development.[19] The

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[17] *See id.* (reporting that feature-based software releases are becoming prevalent in the industry and are being used by large software vendors such as Google).

[18] *See* Samuel J. LaRoque, *Reverse Engineering and Trade Secrets in the Post-Alice World*, 66 U. Kan. L. Rev. 427, 435 (2017); Kaylee Beauchamp, *The Failures of Federalizing Trade Secrets: Why the Defend Trade Secrets Act of 2016 Should Preempt State Law*, 86 Miss. L.J. 1031, 1044 (2017).

[19] *See* David O. Taylor, *Confusing Patent Eligibility*, 84 Tenn. L. Rev. 157, 243 (2016) (reporting on views expressed by patent practitioners concerning the effect of *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), on investment in research and development).

Federal Circuit's decision in this case simply exacerbates these problems.

Computer hardware and consumer electronics constitute yet another industry sector in which the impact of globalization is clearly evident. Unlike the original Macintosh computer that was built in California, today's iPhone is not only built abroad but includes electronic components from companies in many foreign countries.[20] The emergence of state-of-the-art fabrication-only facilities across the world has allowed semiconductor design and development to occur essentially anywhere in the world.[21] It is not uncommon for semiconductor companies, especially startups, to enter into confidential supply agreements with foreign suppliers for chip fabrication. *Id.* For today's complex consumer electronics, lead times from execution of such agreements to those components being used within

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[20] *See* David Barboza, *An iPhone's Journey, From the Factory Floor to the Retail Store*, The New York Times (Dec. 29, 2016) (reporting that Apple buys many of the components for iPhones from more than 200 suppliers around the world).

[21] Erol C. Basol, *Fabless Semiconductor Companies, the Patent On Sale Bar, and the New America Invents Act: Have Fabless Companies Been Shortchanged, or Is Change Coming?*, 16 UCLA J.L. & Tech. 1, 3 (Fall 2012) (explaining that the new model has allowed for smaller "fabless" semiconductor design companies to focuses solely on designing and developing new technologies and then contracting with companies that have fabrication facilities to produce the designs).

a publicly available final product can be significant. The Federal Circuit's ruling would prematurely trigger the on-sale bar based on such supply agreements, thereby depriving fabless players in the semiconductor industry from patent protection for their designs.[22]

The on-sale bar "seek[s] both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 65 (1998). In each of the instances of third-party collaboration discussed above, there is no "knowledge already in the public domain" that needs to be protected by barring a patent. The Federal Circuit's decision therefore ignores this Court's stated policy underlying the on-sale bar.

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[22] *See id.* at 7, 23 (discussing that no exception exists under Federal Circuit precedent to prevent such supplier agreements from triggering the pre-AIA on-sale bar and hoping that the AIA fixed the problem) (citing *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001)).

IV. The Federal Circuit's interpretation would defeat the AIA's goal of harmonizing the U.S. patent system with those in other developed countries.

Through the enactment of the AIA, Congress intended to resolve differences between the patent laws of the United States and those of the rest of the industrialized world, thereby promoting greater international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries. AIA § 3(p). While the most significant change that the AIA made in this regard was converting the United States patent system from "first to invent" to a system of "first inventor to file," *id.*, another difference that it sought to resolve was that the rest of the world requires public disclosure in order for an activity to be patent-barring. *See* The Naples Roundtable Cert. Br. at 11–19 (discussing patent systems in Europe, China, Republic of Korea, and Japan—countries that, together with the United States, handle the vast majority of the world's patent applications). Patent examination guidelines from these countries make clear that agreements to maintain secrecy—even tacit ones—are effective to keep the subject matter out of the prior art.[23] Inventors who regularly

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[23] *See, e.g.*, State Intellectual Property Office of the People's

file patent applications under these systems undoubtedly have an expectation that secret activities, including secret sales, do not place their inventions in the public domain. United States inventors, on the other hand, have long risked patent forfeiture based on a hindsight analysis of a secret offer to sell the invention. Congress clearly intended to eliminate this glaring inconsistency in view of the AIA's expressed goal to promote "uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries." AIA § 3(p).

The Federal Circuit's decision, on the contrary, broadens the disparity with global patent systems by expanding the scope of pre-AIA secret sales to include ones made outside of the United States. *See supra* Section II.A. For example, a confidential supply agreement or license agreement entered into in Beijing, one clearly not considered to be a patent-barring activity in China (or any other developed country), could now bar a U.S. patent filed a year later.

Republic of China, Guidelines for Patent Examination 171–72 (2010), available at http://www.sipo.gov.cn/zlsqzn/sczn2010-eng.pdf (excluding from prior art activity conducted in situations "where the obligation to keep secret arises from social customs or commercial practices, that is, from implicit agreements or understandings.").

Moreover, before the AIA "depositions and litigation discovery [were] required in order to identify all of the inventor's private dealings with third parties and determine whether those dealings constitute a secret offer for sale or third party use that invalidates the patent."[24] Under the Federal Circuit's rule, this discovery may now have to be conducted at a global level—including in countries that find such discovery entirely unnecessary—dramatically increasing the time and cost of litigation to resolve on-sale bar issues.

The disparity in secret prior art laws created by the Federal Circuit's decision makes it harder to obtain patent protection or enforce patent rights in the United States than in much of the rest of the world, consequently weakening our patent system and extending its decline among those of rest of the world.[25]

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[24] 157 Cong. Rec. S5319, S5319–21 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl).

[25] *See* Create, U.S. Chamber of Commerce's International IP Index, at 35-36 (Feb. 2018), at http://www.theglobal-ipcenter.com/wp-content/uploads/2018/02/GIPC_IP_Index_20-18.pdf (ranking the U.S. patent system at *twelfth* in the world and attributing its decline to the uncertainty of our patentability standards and the ease with which U.S. patents can be invalidated).

CONCLUSION

HIPLA respectfully asks this Court to rule that that an offer for sale or sale of an invention to a third party that does not result in public disclosure of the invention does not qualify as prior art under 35 U.S.C. § 102(a).

Respectfully submitted,

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August 30, 2018

NO. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., ET AL.,
Respondent.

On Writ of *Certiorari* to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* IEEE-USA IN SUPPORT OF AFFIRMANCE

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16 October 2018

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INTEREST OF *AMICUS CURIAE* [1]

IEEE-USA is an organizational unit of The Institute of Electrical and Electronics Engineers, Inc. (IEEE), the world's largest technical professional organization dedicated to advancing technology for the benefit of humanity. IEEE-USA supports the nation's prosperity and competiveness by fostering technological innovation for the benefit of all, including nearly 200,000 U.S. engineers, scientists, and allied professionals who are members of the IEEE.

As part of its mission, IEEE-USA seeks to ensure that U.S. intellectual property law "promote[s] the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. Art. I, § 8. IEEE-USA's members have a substantial stake in the U.S. patent system. Our membership includes inventors who create and use cutting-edge technology, researchers who are involved in scientific discovery, authors of

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[1] Pursuant to Supreme Court Rule 37.6, counsel for the *amicus curiae* certifies that no counsel for any party authored this brief in whole or in part and that no person or entity other than the *amicus*, its membership, or its counsel made a monetary contribution intended to fund the preparation or submission of the brief. The parties have filed blanket consents to the filing of *amicus* briefs and their letters are filed with the clerk.

journal articles in the broad fields of engineering and science, entrepreneurs, and employees of firms that acquire, license, and market patented technology. IEEE-USA has consistently advocated for the full legislative restoration of the pre-AIA American grace period, which neither parties' statutory construction of the AIA achieves.[2] While IEEE-USA supports Respondent on the statutory construction question presented, we take no position on the ultimate question of the validity or infringement of the patents at issue in this case.

SUMMARY OF ARGUMENT

Does U.S. patent law under the America Invents Act of 2011 ("AIA") permit the issuance of patents to inventors after they have had an unlimited exclusive period of secret commercialization of the invention? *Amicus* IEEE-USA argues that the answer is 'No' – the same answer as that held by the courts before enactment of the AIA. Under the same principles, this brief also argues that the AIA did not change the "experimental use" doctrine that protects inventors during their pre-filing activities for testing and perfecting their inventions.

For more than two centuries, American patent law provided that an inventor forfeits the right to a patent for his invention that had been "on sale" or in

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[2] *See* IEEE-USA, *Patent Prior Art and Grace Period, Position Statement*, (November 18, 2016), available http://ieeeusa.org/wp-content/uploads/2017/02/PriorArt1116.pdf

"public use" longer than a set grace period before the filing date of his patent application. That is so even if such sale or use did not disclose to the public the invention. Petitioner Helsinn argues that the change in the statute under the AIA must be read as having repealed this forfeiture bar – that as long as the invention is not disclosed to the public, secret commercialization of an invention does not bar patenting it any time later. Examples of inventions in this secret commercial use category are methods of manufacture, process of making, or composition of matter, which cannot be learned from the end product used by, or sold to, the public.

The Federal Circuit correctly held otherwise and rejected the argument that the AIA repealed the secret commercialization forfeiture bar. This Brief urges affirmance of that decision. The Brief marshals evidence and a constitutional avoidance doctrine to show that Congress neither intended to change, nor changed, the meaning of the statutory terms "on sale" and "public use" in the AIA statute.

The Brief shows that under the Petitioner's alternative construction, there would be substantial disruption to innovation because the statute may plausibly be interpreted as foreclosing on the "experimental use" exception to "on sale" and "public use," causing massive loss of patent rights.

ARGUMENT

This case presents an important question: did the meaning of the statutory terms of art "on sale" and "public use" in the patent law change under the America Invents Act, PL 112-29, 125 Stat. 284 (2011) ("AIA")? *Amicus curiae* IEEE-USA shows below that the answer is decidedly "No." The Federal Circuit correctly held that "the AIA did not change the statutory meaning of 'on sale' in the circumstances involved here." *Helsinn Healthcare v. Teva Pharmaceuticals*, 855 F.3d 1356, 1360 (Fed. Cir. 2017).

Although the Question Presented in this case is limited to the statutory meaning of "on sale" in post-AIA § 102(a)(1), the immediately-preceding term in the text, "public use," is subject to identical statutory construction principles due to its location in the sentence and due to its having been invoked as a counterpart to the "on sale" personal bar against the inventor under identical patent policy principles. Because it is imperative that any ambiguities in the post-AIA statute of Section 102(a)(1) be resolved with finality, this Court's decision should address both terms. For this reason, this brief addresses both the "on sale" and the "public use" bars as counterparts.

I. THE TERMS "ON SALE" AND "PUBLIC USE" ARE INGRAINED IN THE FABRIC OF THE AMERICAN INNOVATION PRACTICE

Over nearly two centuries of American jurisprudence, the statutory terms "public use" and "on sale" in patent law have received specific and well-established meanings. Those were laid out in precedential case law spanning more than 640 federal cases identified in the American Law Reports. William G. Phelps, "When does on–sale bar of § 102(b) [ ] prevent issuance of valid patent," 155 *A.L.R. Fed.* 1 (2010); Kurtis A. Kemper, "When is Public Use [ ] for Experimental Purposes, so that § 102(b) Does Not Prevent Issuance of Valid Patent," 171 *A.L.R. Fed.* 39 (2010). These statutory terms, their interpretation, and recognized related exceptions govern the established practices and conduct of technology developers in perfecting, commercializing, testing, disclosing, promoting, and marketing their inventions. Over decades, American industries have built procedures for inter-company contracting, disclosure, collaboration, and structuring business transactions based on the settled interpretation of these statutory terms.

Under pre-AIA law, a definite sale or an offer for sale of the invention prior to the critical date need not itself disclose the claimed invention to make the patent invalid under the "on–sale" bar. *Pennock v. Dialogue*, 27 U.S. 1, 19 (1829) (Invalidating a patent when inventor commercially exploited the invention and withheld from "the public the secrets of [the] invention."); *RCA Corp. v. Data General Corp.*, 887

F.2d 1056, 1060 (Fed.Cir.1989), *different part overruled* by *Group One v. Hallmark*, 254 F.3d 1041 (Fed.Cir.2001). Where an inventive method is kept secret, and remains secret after a sale of the product of the method, that sale will not bar another inventor from patenting that method. It will, however, bar a patent if that sale of the product was made before the critical date by the applicant for that patent or its assignee. *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144 (Fed.Cir.1983). It was not required that members of the public be aware that the product "on sale" actually embodies the claimed invention. *Abbott Laboratories v. Geneva Pharmaceuticals, Inc.*, 182 F.3d 1315, 1317–18 (Fed. Cir. 1999). Indeed, a long line of precedent holds that secret commercialization by the inventor bars patentability. "If an inventor should be permitted to hold back from the knowledge of the public the secrets of his invention," commercially exploit it exclusively and later "take out a patent," that "would materially retard 'the progress of ... the useful arts'" and "give a premium to those ... least prompt to communicate their discoveries." *Pennock*, 27 U.S. at 19 (Story, J.) (quoting U.S. Const. Art. I, §8, cl. 8). Courts have thus adhered to an equitable maxim that "[i]t is a condition upon the inventor's right to a patent that he shall not exploit his discovery competitively after it is ready for patenting; he must content himself with either secrecy or legal monopoly." *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2nd Cir. 1946) (Learned Hand, J.), *cert. denied*, 328 U.S. 840 (1946); *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 149 (1989) (quoting *Metallizing* with approval); *Pfaff v. Wells Elecs., Inc.*,

525 U.S. 55, 68 (1998) (quoting *Metallizing* with approval).

Similarly, under pre-AIA law, it is unnecessary for an invention to be disclosed while in "use" to be considered "public" so as to bar a patent under pre-AIA 35 U.S.C. § 102(b)—the invention need only be accessible to the public, even if access to the information is practically infeasible. *Hall v. Macneale*, 107 U.S. 90, 96 (1883) (inventor's three "burglar-proof" safes were in public use, despite the invention being completely concealed within safe); *New Railhead Mfg. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 1299 (Fed. Cir. 2002) (patent held invalid for public use even though drill bit invention operating underground could not be viewed in operation). "It is not public knowledge of his invention that precludes the inventor from obtaining a patent for it, but a public use or sale of it." *TP Labs., Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 970 (Fed.Cir.1984). The term 'public' means merely 'not secret.' *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1549 (Fed.Cir.1983) ("The nonsecret use of a claimed process in the usual course of producing articles for commercial purposes is a public use"). Use of an invention is deemed not secret when "used by a person other than the inventor who is under no limitation, restriction, or obligation of secrecy to the inventor." *In re Smith*, 714 F.2d 1127, 1134 (Fed.Cir.1983) (citing *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881)).

For over more than a century, courts have also recognized the equitable doctrine of the "experimental use" exception to the "on sale" and

"public use" bars. It is a settled safe harbor during a limited period for a bona fide experimental purpose of testing or perfecting the invention rather than using it for commercial exploitation. According to the experimental use exception, such invention-disclosing public-use would not bar a patent. *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1877) (A patent for an improved pavement held valid even though the segment of the pavement about 75 feet in length on a road by way of experiment was publicly used). Similarly, where a sale is primarily for a bona fide experimental purpose to test or perfect the invention rather than for commercial exploitation, the prior sale does not bar patent validity. *A.B. Chance Co. v. RTE Corp.*, 854 F.2d 1307, 1311 (Fed.Cir.1988). *Envirotech Corp. v. Westech Eng'g Inc.*, 904 F.2d 1571, 1574 (Fed. Cir. 1990).

Generally, the time limit for filing a patent application after its first public use or commercial exploitation is set by a congressional policy grounded in the U.S. Constitution, as suggested in *Pennock*. From the Patent Act of 1790 to the present day, any sale or public use of an article ready for patenting, if not closely followed by filing a patent application, has acted as a *forfeiture* of patent protection for any invention embodied in the article or its manufacture. "[T]he inventor who designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public comes not within the policy or objects of the Constitution or acts of Congress. He does not promote, and, if aided in his design, would impede, the progress of science

and the useful arts." *Kendall v. Winsor*, 62 U.S. 322, 328 (1858) (citing U.S. Const. art. I, § 8, cl. 8).

Section 102(b) under pre-AIA law "is primarily concerned with the policy that encourages an inventor to enter the patent system *promptly*." *Woodland Tr. v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998) (emphasis added). "Thus an inventor's own prior commercial use, albeit kept secret, may constitute a public use or sale under § 102(b), barring him from obtaining a patent." *Id.* This bar is part of the *quid pro quo* of the patent bargain – "it is part of the consideration for a patent that the public shall *as soon as possible begin* to enjoy the disclosure. *Metallizing*, 153 F.2d at 520 (Learned Hand, J.) (emphasis added). Repealing this bar may result in *indefinite* "practical monopoly by means of secrecy and of a later legal monopoly by means of a patent." *Metallizing*, 153 F.2d at 519.

Thus, the "on sale" and "public use" equitable forfeiture bars to patentability are distinct from *prior art* bars. Quite apart from any *disclosure* considerations, "on sale" and "public use" in this context define commercial *conduct* under which the inventor *forfeits* the right to a patent when balancing the equities of the inventor and the public. This balance is *a matter of policy* grounded in our Constitution. For reasons explained below, these sound constitutionally-grounded policies were not repealed by Congress' enactment of the AIA in 2011.

II. CONGRESS DID NOT CHANGE THE MEANING OF "ON-SALE" AND "PUBLIC USE" IN ENACTING THE AIA

Post-AIA 35 U.S.C. § 102(a)(1) bars a patent if "the claimed invention was patented, described in a printed publication, or in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention." (Emphasis added).

The plain language here shows that Congress did not overturn the settled meaning of "on sale" and "public use" by adding the new residual category "or otherwise available to the public." This new term is a disjunctive that captures disclosures through media and modalities that are not in patents, "in a printed publication," or in "public use."

II.A The residual term "otherwise available to the public" covers a growing non-overlapping category of prior art.

Helsinn's interpretation does not merely change the settled meaning of the terms "on sale" and "public use;" its interpretation (at 4) that perverts the "new catch-all provision" as a clarification that "informs the meaning of the language that precedes it" sidesteps the congressional purpose of explicitly providing for the residual prior art category. For example, the IEEE Collabratec® integrated online community platform connects technology professionals all over the world.[3] In 2017 alone, its

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[3] *See* http://ieee-collabratec.ieee.org/

user base grew by 61 percent to include more than 120,000 registered users. [4] This online platform facilitates sharing knowledge and expertise through globally diverse, engineering-focused communities. A technical item shared with other users on the IEEE Collabratec® platform is not literally a "printed publication." And when operating on user device "apps," which are *not* webpages *per se*, such sharing may *not* be necessarily construed as judicially-recognized equivalent of a "printed publication."[5] Clarifying the scope of the prior art to include public disclosure in such new technological modalities is the purpose of the AIA's residual category of "otherwise available to the public;" Congress' purpose was to update the statute to cover emerging public dissemination technologies since the Patent Act of 1952.

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[4] IEEE, *Annual Report 2017*, at 23.

[5] The Federal Circuit has held such equivalence even for unindexed public sources on the internet, *e.g.*, *Voter Verified, Inc. v. Premier Election Solutions, Inc.*, 698 F.3d 1374, 1379–81 (Fed. Cir. 2012) (holding that content on a "website" is "printed publication"); *Suffolk Techs., LLC v. AOL Inc.*, 752 F.3d 1358, 1364–65 (Fed. Cir. 2014) (holding that a Usenet newsgroup posting is "a printed publication.")

II.B The doctrine of constitutional avoidance counsels statutory construction that preserves the settled meaning of "on sale" and "public use"

Apart from fundamental conflicts with statutory construction principles discussed in the briefs of the Respondent and its other *amici*, Helsinn's construction of Post-AIA § 102(a)(1) raises serious constitutional questions. This is because such construction repeals the forfeiture bars to patenting, which may exceed the Constitutional "limited times" notion and the "progress" limits on Congress' authority. As Justice Story explained in *Pennock*, allowing the inventor "for a long period of years" to "retain the monopoly and make and sell the invention publicly, and thus gather the whole profits of it," and thereafter allowing him "to take out a patent, and thus exclude the public from any further use than what should be derived under it during" the patent term, "would materially retard the progress of science and the useful arts and give a premium to those who should be least prompt to communicate their discoveries." *Pennock*, 27 U.S. at 19 (Story, J.) (quoting U.S. Const. Art. I, §8, cl. 8). Thus, by allowing the inventor to delay without bound the disclosure of the invention, Congress would "not promote," but "would impede, the progress of science and the useful arts." *Kendall* 62 U.S. at 328 (citing U.S. Const. art. I, § 8, cl. 8). *See* Ron D. Katznelson, "The America Invents Act May Be Constitutionally Infirm if It Repeals the Bar Against Patenting After Secret Commercial Use," 13 *Engage: J. Federal Society Practice Groups*, 73, 74-76 (October 2012); D.H. Crawley, "America Invents Act: Promoting

Progress or Spurring Secrecy?," 36 *U. Haw. L. Rev.* 1, 24-25 (2014) (allowing "patenting even after years of secret commercialization" would violate "the constitutional mandate"; "Without the public disclosure of patenting, other inventors cannot build on the invention to advance technology, and the progress of science and the useful arts is retarded, not promoted.")

The U.S. Constitution cabins Congress' power, restricting it to "securing for *limited times* to authors and inventors the *exclusive right.*" That restriction on Congressional power is not confined merely to securing exclusive rights in issued patents – it also encompasses any de-facto pre-issuance exclusivity that Congress may indirectly "secure" by incentives created by its statutory scheme that controls inventors' rights and obligations prior to filing. Helsinn's construction of post-AIA § 102(a)(1), however, would do just that. It would hold that Congress authorized inventors to receive a patent after an *indefinite* period of secret *exclusive* exploitation of their invention, and therefore necessarily *secured* the *exclusive* period for an *indefinite* duration at the *inventors'* discretion. *Metallizing*, 153 F.2d at 520 (Learned Hand, J.) (by "making use of his secret to gain a competitive advantage over others," the inventor would "thereby extend the period of his monopoly"); *See* Katznelson, *Supra.* at 76. This de facto indefinite extension of exclusive use of the invention in a cascade that ends with a full patent term is distinguishable from extending it by a *set* duration. *Cf. McClurg v. Kingsland*, 42 U.S. 202, 206 (1843) (sustaining a limited extension of existing patent terms); *Eldred v.*

Ashcroft, 537 U.S. 186, 209-10 (2003) (existing copyright terms extended 20 years by Congress remained "limited," not "perpetual"). Helsinn's construction thus raises a substantial constitutional question.

"It is a time-honored doctrine that statutes and regulations are first examined by a reviewing court to see if constitutional questions can be avoided." *Wyman v. James*, 400 U.S. 309, 345 n.7 (1971) (citing *Ashwander v. TVA*, 297 U.S. 288, 345-48 (1936) (Brandeis, J., concurring)). *Crowell v. Benson*, 285 U.S. 22, 62 (1932) ("When the validity of an act of the Congress is drawn in question, and even if a serious doubt of constitutionality is raised, it is a cardinal principle that this Court will first ascertain whether a construction of the statute is fairly possible by which the question may be avoided."). The premise of constitutional avoidance is that "Congress did not intend" any meaning of a statute "which raises serious constitutional doubts." *Clark v. Martinez*, 543 U.S. 371, 381 (2005). While the courts must grant the AIA the full measure of deference owed to federal statutes, if a construction of post-AIA § 102(a)(1) appears unconstitutional, this Court has explained that "every reasonable construction must be resorted to, in order to save a statute from unconstitutionality." *Hooper v. California*, 155 U. S. 648, 657 (1895); Courts need not determine that the statute as construed by Helsinn would be unconstitutional; they are merely "obligated to adopt a saving construction ... ." *SKF USA, Inc. v. U.S. Customs & Border Prot.*, 556 F.3d 1337, 1349-50 (Fed. Cir. 2009) ("While we need not go so far to

sustain the statute here, ... the doctrine of constitutional avoidance is not 'irrelevant'.")

III. CONGRESS NEITHER CONSIDERED NOR INTENDED THE COLLATERAL ABANDONMENT OF THE "EXPERIMENTAL USE" DOCTRINE THAT IS INEXTRICABLY LINKED TO THE SETTLED MEANING OF "ON SALE" AND "PUBLIC USE."

Congress never enunciated in the legislative history of the AIA the construction of § 102(a)(1) of "otherwise available to the public" as Helsinn now advocates. Such a construction would eviscerate the carve-out in the nearly two centuries-old settled safe harbor of the "experimental use" doctrine discussed in I above.

Under the "experimental use" exception, "an inventor who seeks to perfect his discovery may conduct extensive testing without losing his right to obtain a patent for his invention — even if such testing occurs in the public eye." *Pfaff*, 525 U.S. at 64; *City of Elizabeth*, 97 U.S. at 133-34; *Kendall*, 62 U.S. at 328-9 (The inventor's obligations for securing a patent "by no means forbid a delay requisite for completing an invention, or for a test of its value or success by a series of sufficient and practical experiments... [which] may be highly advantageous, as tending to the perfecting the invention"); *Pennock*, 27 U.S. at 18-19 (Story, J.) ("The use, as well as the knowledge of his invention, must be indispensable to enable him to ascertain its competency to the end proposed, as well as to perfect

its component parts. The words ['not known or used before the application'] then, to have any rational interpretation, must mean, not known or used by others, before the application.") Proof of experimental use before the invention is ready for patenting serves "as a negation of the statutory bars." ***EZ Dock v. Schafer Sys., Inc.***, 276 F.3d 1347, 1352 (Fed. Cir. 2002). A use may be experimental if its purpose is: "(1) [to] test claimed features of the invention or (2) to determine whether an invention will work for its intended purpose — itself a requirement of patentability." ***Clock Spring, L.P. v. Wrapmaster, Inc.***, 560 F.3d 1317, 1327 (Fed. Cir. 2009). The purpose of this doctrine is to discourage "paper inventions," sketchy disclosures and incomplete patent applications. It encourages experimentation, field testing under service conditions, and efforts to perfect an invention.

In ***Polara Engineering Inc v. Campbell Co.***, 894 F.3d 1339 (Fed. Cir. 2018), the Federal Circuit described the relevant factors that courts should consider to assess the existence of a bona fide experimental use. These factors include "(1) the necessity for the public testing, (2) the amount of control over the experiment retained by the inventor, (3) the nature of the invention, (4) the length of the test period, (5) whether any payment was made, (6) whether there was a secrecy obligation, (7) whether records of the experiment were kept, (8) who conducted the experiment, (9) the degree of commercial exploitation during testing, (10) whether the invention reasonably requires evaluation under actual conditions of use, (11) whether testing was systematically performed, (12) whether the inventor

continually monitored the invention during testing, and (13) the nature of contacts made with potential customers." *Id.* at 1348 (citing *Clock Spring,* 560 F.3d at 1327).

However, under Helsinn's theory that the AIA *substantively* modified the terms "on sale" and "public use" to bar patentability due to any activity that makes the invention "otherwise available to the public," the inquiry under the Federal Circuit's 13 factors listed above would be abrogated as irrelevant because of this catch-all *literal* statutory bar to patentability. In other words, it would be wholly illogical to assume that absent any statutory guidance, the AIA's "otherwise available to the public" clause arbitrarily altered the "on sale" bar only in the manner that Helsinn favors, but not in the manner that also repeals the experimental use doctrine. Indeed, Helsinn is silent on the experimental use doctrine, let alone explaining why courts should continue to consider *Clock Spring's* Factor 9 – "the degree of commercial exploitation during testing" – but totally ignore such factor during an indefinite secret commercialization, as would be required under the repeal of *Metallizing*.

Accordingly, the interpretation urged by Helsinn, should this Court adopt it, would repeal the experimental use exception and would lead to frequent loss of patent rights. It would fundamentally disrupt research, development, management and many established engineering procedures in industries. It would also undermine optimizing inventions for maximum public safety.

For example, in *Polara Engineering*, the invention of accessible pedestrian signal systems and pedestrian push buttons related to public safety in crossing the street. The inventors "needed to ensure the invention's durability and safety before being certain that it would work for its intended purpose." *Polara*, 894 F.3d, at 1350. "[D]urability and safety of the system could not be ascertained without it being subjected to use for a considerable period of time under different actual use conditions, *e.g.*, different crosswalk sizes and configurations and different environments. Experimenting under actual use conditions necessitated that the testing occur at public intersections." *Id.* at 1350. Under Helsinn's interpretation of the statute, inventions such as Polara's would not be perfected, nor patented, because the necessary experimentation would make the invention "available to the public."

In the biomedical technologies requiring FDA approval, the sheer number of people involved and the public nature of the testing in large-scale trials to generate the necessary clinical data required by the FDA is similarly likely to make the invention "available to the public." In addition, medical device manufacturers may need to charge the investigators performing the clinical testing or the patients for the new medical device in order to defray costs. While under some criteria the invention would be later (in hindsight) considered to have been ready for patenting before trials began, until clinical testing on humans, it may not be known whether the inventive device or treatment produce unwanted side effects even though it might work for the intended purpose. Additional iteration of the invention might

be required before the filing of an application that adequately "describe[s] the manner and process of making and using the invention so as to enable a person of skill in the art to make and use the full scope of the invention *without undue experimentation*." *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1344–45 (Fed. Cir. 2005) (emphasis added). Thus, under Helsinn's construction, such public experimentation may not be possible without the loss of patent rights.

Apparently, none of these impediments to entire industries were discussed during the AIA's legislative process. Congress gave no consideration to applicants' reliance on "experimental use" for perfecting and vetting inventions prior to filing complex patent applications. These issues are but the tip of an iceberg. Congress could not have intended to undermine entire industries and their innovation business conduct by foreclosing on the "experimental use" through stealth parsing of sentence text and grammatical punctuation exercises. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes."); *Kellogg Brown & Root Servs., Inc. v. U.S., ex rel. Carter*, 135 S. Ct. 1970, 1977 (2015) ("Fundamental changes in the scope of a statute are not typically accomplished with so subtle a move.")

IV. CONGRESS DID NOT INTEND TO REPEAL THE PATENT FORFEITURE BARS

Throughout Congress' patent policy trajectory over the years one sees consistent efforts to maintain, if not strengthen, the forfeiture bars against pre-grant delays after invention; taken as a whole, Congress did not disturb the established meaning of the terms "on sale" and "public use."

IV.A Helsinn's purported repeal permits an *indefinite* grace period for secret exploitation of inventions for which Congress evidenced no intention

Helsinn's theory that the AIA repealed the patent forfeiture bars for secret commercialization and non-informing public use would permit inventors to secretly practice an invention indefinitely prior to filing an application, effectively making the pre-AIA's one-year grace period for such activities *indefinite* under post-AIA law. If that were truly a goal of the AIA, which it is not, it would prove a radical departure from Congress' clear historical policy record since the mid-19th century. Congress' policy record has been that of *shortening*—not extending—the exclusive period from invention to patent expiration. This is shown in statutes that shortened the permitted period between invention and filing, between filing and patent issuance, or the period over which the patent is in force. The following list is illustrative:

(a) In the Act of March 2, 1861, Ch. 88, § 16, 12 Stat. 249 (1861), Congress repealed patentees' ability to extend their patent term up to 21 years after grant and set the patent term at 17 years from grant.

(b) In the Act of March 3, 1863, Ch. 102, §3, 12 Stat, 796 (1863), Congress shortened the period to pay the patent issue fee to 6 months after allowance, or the application considered abandoned, eliminating applicant practice of delaying the patent issuance.

(c) In the Act of March 3, 1897, Ch. 391, § 4, 29 Stat, 693 (1897), Congress shortened the time to complete an application for examination from 2 years to 1 year after initial filing, and shortened the time to respond to all Office actions from 2 years to 1 year. Failing to meet these deadlines results in forfeiture (abandonment) of the application.

(d) In the Act of May 23, 1908, PL 60-133, Ch. 189, 35 Stat, 246 (1908), Congress provided that patents shall issue 3 months from payment of issue fees, eliminating patent issuance delays by the Patent Office.

(e) In the Act of June 25, 1910, PL 61-296, Ch. 414, 36 Stat, 843 (1910), Congress repealed R.S. § 4902, the statute that allowed inventors to file caveat patent disclosure in the patent office, as means of deferring for up to one year their filing an application, during which time the Patent Office would notify the caveat holder

of any similar applications on the same subject matter if and when filed.

(f) In the Act of March 2, 1927, PL 69-690, Ch. 273, 44 Stat, 1335 (1927), Congress shortened the time to complete an application for examination from 1 year to 6 months after filing, and shortened the time to respond to all Office actions from 1 year to 6 months. Failing to meet these deadlines results in abandonment of the application.

(g) In the Act of August 5, 1939, PL 76-286, Ch. 450, 53 Stat, 1212 (1939), Congress *reduced the grace period* for inventors' disclosures, publications, "on-sale," and "public use" activities from two years to one year before filing an application. "Under present conditions 2 years appears unduly long and operates as a handicap to industry. Reduction of the period would serve *to bring the date of patenting closer to the time when the invention is made*, and would expedite applications, not only in their filing but also in their progress through the Patent Office." S. Rep. 876, 76 Cong. 1st Sess. (July 18, 1939) at 1. (Emphasis added).

(h) In the Act of August 7, 1939, PL 76-341, Ch. 568, 53 Stat, 1254 (1939), Congress provided the Commissioner with authority to set shorter times for reply to an office action not to be less than 30 days and not to exceed 6 months. This flexibility reduces pendency—the total time from filing to patent issuance.

(i) In the Act of August 9, 1939, PL 76-358, Ch. 619, 53 Stat, 1293 (1939), Congress repealed R.S. § 4897, which, as a matter of right, provided for revival of an application for which the issue fee was not timely paid, referring instead the decision to revive to the discretion of the Patent Commissioner. The previous statute "readily permits the deliberate postponement of the issuance of a patent and is resorted to mainly for this purpose. [ ] The proposed change eliminates renewals, consequently simplifying the practice and abolishing causes and opportunities for delays." S. Rep. 878, 76 Cong. 1st Sess. (July 19, 1939) at 1-2.

(j) In the Patent Fee Act of July 24, 1965, PL 89-83, 79 Stat. 259 (1965), Congress provided that patent issue fee be paid earlier after allowance, with ability for later corrective payment to cover the (initially unknown) printed page count fee component. "This particular arrangement will permit the Patent Office to *issue patents substantially sooner* and make new technology available to the public at an *earlier date*." S. Rep. 301, 89th Cong. 1st Sess. (June 8, 1965) at 5. (Emphasis added).

(k) In the Patent Office Appropriations Act of August 27, 1982, PL 97-247, 96 Stat, 317 (1982), Congress amended 35 U.S.C. § 41 to provide graduated discounted extension-of-time fees to incentivize applicants to reply *sooner* than 6-months to an Office action; it also established escalating maintenance fees to

incentivize *early expiration* of unexploited patents. Both factors have the effect of shortening the exclusive period ending on patent expiration.

(l) In the Uruguay Round Agreements Act of December 8, 1994, PL 103-465, 108 Stat 4809, (1994), Congress changed the term of a patent from 17 years after grant to 20 years counted from the original application date. For substantial number of applications, this had the effect of shortening the exclusive period from invention to patent expiration.

To be sure, Congress also enacted statutes that extend the patent term, but that was to compensate patentees on a day-per-day basis for erosion of their patent term due to unusual government agency delay. *Drug Price Competition and Patent Term Restoration Act of 1984*, PL 98-417, 98 Stat. 1585 (Sept. 24, 1984); *Patent Term Guarantee Act of 1999*, PL 106-113, 113 Stat. 1501A-557 (Nov. 29, 1999).

A repeal of the inventors' forfeiture bars would be an extraordinary departure from Congress' persistence for two centuries in curtailing delays in invention disclosure and patenting. This persistence is unmistakable even leading up to the AIA through previous iterations of patent reform bills that included first-to-file provisions. In adopting and reporting H.R. 1908, a precursor bill to the AIA passed by the House, the House Judiciary Committee Report explained that it "uses the current § 102(b) as the template from which to define the scope of prior art in the Act, primarily

because of how the terms 'in public use' and 'on sale' have been interpreted by the courts." H. Rep. 110–314, 110th Cong. 1st Sess. (Sep. 4, 2007), at 57. The report further explained that the bill's provisions "are meant to ... encourag[e] inventors *to file early* for patent protection, [and] *prevent*[ ] *inventors from extending their monopoly* in the invention." *Id.* (Emphasis added). Notably, the report explains that "there is nothing inherent in a first-to-file system that will deter inventors from making use of their inventions as trade secrets and then some time later filing a patent application for the invention. *Thus, the maintenance* of the "public use" and "on sale" definitions of prior art *are needed to prevent such activity*." *Id.* (Emphasis added).

No proposed congressional policy contradicting this "need to prevent such activity" was subsequently published prior to the enactment of the AIA.

IV.B Congress has not considered the real effects of repealing the secret commercialization patent forfeiture bars

When members and committees of Congress were presented with amendments to the statutory language that would have repealed the patent forfeiture bars for secret commercialization and non-informing public use, they rejected it. See Resp. Br. at 9-12. Indeed, "Congress reject[ed] ... the very language that would have achieved the result [that Helsinn] urges here," which "weighs heavily against [Helsinn's] interpretation." *Hamdan v. Rumsfeld*, 548 U.S. 557, 579-80 (2006). For an industry sector to have pursued such repeal, it would have been

important to explain to members of Congress why the public interest would be better served by permitting an inventor to delay filing of a patent application of an invention that is ready for patenting after commercially exploiting it in secret.

For example, it would have been necessary for chemical companies or pharmaceutical companies to explain that the public interest would be better served if after taking out a patent on a *composition* of a compound or a drug, they would be permitted to keep the *process of making* the compound or the drug a trade secret, and still be allowed years later to file and obtain a patent on that *process*. In some circumstances, this policy would allow daisy-chaining and extending patent protection beyond an intended legislated term. There is no evidence that a case was ever made to Congress for such policy prior to the enactment of the AIA.

Instead, the dominant policy matters discussed in Congress in the years leading up to the AIA with respect to amending § 102 were matters regarding the First-to-File vs. the First-to-Invent systems, interferences, the virtual elimination of the grace period, and *other* effects of the redefinition of prior art. The prospect of allowing—even incentivizing—inventors to delay for years filing patent applications is inconsistent with a stated goal of prompt filing of patent applications. S. Rep. 110-259, 110th Cong. 2nd Sess. (Jan. 24, 2008) at 7 ("[A] first to file system encourages the *prompt* filing of patent applications.") (Emphasis added); H. Rep. 110–314, 110th Cong. 1st Sess. (Sep. 4, 2007) at 57 ("The [first-to-file] provisions ... are meant to serve a set of very specific

policy goals [including] encouraging inventors to *file early* for patent protection"). (Emphasis added).

Indeed, the proposals made in policy studies recommending patent reforms and the AIA's legislative history during 2005-2011, including congressional bills and committee hearings, were analyzed in detail. The analysis reveals that neither the notion nor the implications of repealing the "on sale" and "public use" forfeiture bars were ever brought up before Congress. *See* Daniel Taskalos, "Metallizing Engineering's Forfeiture Doctrine After the America Invents Act, 16 *Stan. Tech. L. Rev.* 657, 680-700 (2013).

IV.C Congress could not have intended to effectuate the policies underlying the repeal of the forfeiture bars

Were the Court to adopt Helsinn's construction of the statute, it would enable companies to extend their commercial exclusivity indefinitely by hoarding, exploiting, and profiting secretly from certain technologies for years and then taking out patents on these technologies. It would also permit market incumbent companies to "evergreen" their old secret technologies into a windfall of patents on subject matter for which patent protection had long been forfeited under pre-AIA law. This windfall will disproportionately enrich older and established market incumbents to the detriment of early-stage startups that are too young to have accumulated older secret technology.

Judge Markey remarked: "[O]ur Forefathers had some experience with that from the Guilds in Europe

and did not want a secret technology. They created the patent system to encourage disclosures." Howard T. Markey, "Some Patent Problems," 80 *F.R.D.* 203, 206 (1978) (discussing the patent bargain).

If inventors are afforded unlimited or unspecified exclusive period to commercially exploit their inventions in secret, they would have less incentives to disclose their invention early. *Pennock*, 27 U.S. at 19; Katznelson, *supra*, at 89; Crawley, *supra*, at 24. Consequently, substantial duplication of R&D may ensue; and those participating in the patent system—those patent seekers who disclose early—would be subject to greater risks. First, there would be an asymmetric flow of information to the hoarder of secrets—the only beneficiary from this information exchange. Second, because those seeking patents must disclose their technology and its progression, the hoarder of secrets can ambush the patent-seeker by tracking their progress and preemptively filing a patent application whenever it appears that the patent seeker is close to discovering the undisclosed subject matter possessed by the hoarder of secrets. That would tip the balance of risks against those who participate in the patent system. This is akin to card players in a rigged game wherein one player is subject to a rule requiring him to reveal his hand to his opponent who is not subject to that same disclosure rule and thus keeps his hand secret. This shift of risks from those who hoard secrets to those who participate in the patent system is nothing short of a recipe for undermining the American patent system.

IV.D Congress has not abandoned the equitable common-law rules that continue to operate alongside the statutory terms

The pre-AIA patent-defeating statutory language invoking the terms "on sale" and "public use" does not expressly distinguish between pre-filing use of the invention by the inventor over that of others. Yet, courts have acknowledged that a construction that makes such distinction is necessary on *equitable grounds* to serve the same policy goals embodied in the statutory bars. *Pennock*, 27 U.S. at 18-19 (Story, J.); *Pfaff*, 525 U.S. at 64; *City of Elizabeth*, 97 U.S. at 133-34; *Kendall*, 62 U.S. at 328-9 ; *D.L. Auld*, 714 F.2d at 1148; *Metallizing*, 153 F.2d at 520. Such distinction leading to the equitable forfeiture bar and the experimental use exception is inherently under the *inventor's* control, not the public, over conduct that leads to sales and public use of his invention; this distinction is necessary when applying the principles of equity to curtail inventor's opportunism in extending the effective exclusive period. *Id.* at 520 (by "making use of his secret to gain a competitive advantage over others," the inventor would "thereby extend the period of his monopoly").

Because the relevant circumstances and dispositive evidence in such pre-patenting activities are case-specific and span a wide spectrum of relevant factors, the breadth and flexibility of equitable doctrines must apply alongside the statute for "avoiding mechanical rules." *Holland v. Florida*, 560 U.S. 631, 650 (2010) (citing, e.g., *Hazel-Atlas Glass*

Co. v. Hartford-Empire Co., 322 U.S. 238, 248 (1944) (doctrines of equity are used to "relieve hardships which, from time to time, arise from a hard and fast adherence" to absolute legal rules, which, if strictly applied, threaten the "evils of archaic rigidity"); *Swann v. Charlotte-Mecklenburg Bd. of Educ.*, 402 U.S. 1, 15 (1971) (declaring that "breadth and flexibility are inherent in equitable remedies").

The need for avoiding the "evils of archaic rigidity" by employing equitable factors is not unique to the proper interpretation of the statutory patenting bars. Indeed, analysis of this Court's jurisprudence over the last several decades illustrates this Court's general equity-protective presumption in interpreting federal statutes. *See* Leigh T. Anenson, "Statutory Interpretation, Judicial Discretion, and Equitable Defenses," 79 *U. Pitt. L. Rev.* 1, 21-24 (2017). In fact, because of the need for "avoiding mechanical rules," this approach for ascertaining statutory meaning is an instrument on which Congress relies. *Astoria Fed. Sav. & Loan Assn. v. Solimino*, 501 U.S. 104, 108 (1991) ("Congress is understood to legislate against a background of common-law adjudicatory principles" and to incorporate them "except when a statutory purpose to the contrary is evident" (internal quotation marks and citation omitted)). "In order to abrogate a common-law principle, the statute must 'speak directly' to the question addressed by the common law." *United States v. Texas*, 507 U.S. 529, 534 (1993) (citation omitted); *Beck v. Prupos*, 529 U.S. 494, 500 (2000) ("[W]hen Congress uses language with a settled meaning at common law, Congress presumably knows and adopts the cluster of ideas

that were attached to each borrowed word in the body of learning from which it was taken and the meaning its use will convey to the judicial mind unless otherwise instructed. In such case, absence of contrary direction may be taken as satisfaction with widely accepted definitions, not as a departure from them.") (quoting *Morissette v. United States*, 342 U.S. 246, 263 (1952), quotation marks omitted).

This was Congress' statutory approach in Section 102(b) of the Patent Act of 1952, incorporating the equitable doctrines surrounding the forfeiture bars and experimental use exceptions thereto long after they were well-developed judicially, and subsequently its approach in retaining the common law and these equitable doctrines by preserving the terms "on sale" and "public use" in the AIA.

Helsinn acknowledges that the post-AIA statute "can encompass items 'not specifically enumerated' in a statute." Pet. Br. at 36. Helsinn's theory, however, is that by inserting the AIA's modifier "otherwise available to the public," Congress jettisoned the equity-protective presumption in interpreting the statutory terms "on sale" and "public use" as being unnecessary — that the statutory change and the first to file system leave no room for the pre-AIA equitable factors. Hence, Helsinn counterfactually posits:

> "[the shift to the first to file system] fundamentally altered the justification for the on-sale bar. Before the AIA, when patentability hinged on who was first to invent, an inventor could effectively extend the available patent

> term by selling the invention in secret. Under the AIA, however, an inventor who does not immediately file for a patent takes the risk that another inventor will file the first patent application and thus have priority. As a result, it is unnecessary for the on-sale bar to provide inventors with an additional incentive to enter the patent system promptly."

Pet. Br. at 16. This is a non-sequitur because the AIA's first to file rule does *not* change the fact that under Helsinn's construction, the inventor can still "effectively extend the available patent term by selling the invention in secret." Under this construction, filing delay is actually incentivized, not merely for the one-year pre-AIA grace period, but for an *unbounded* period.

That the first to file provision alone does not materially change the policy animating the equitable forfeiture bars is clear from the House explanation for maintaining the "on sale" and "public use" terms in the AIA's predecessor H.R. 1908, which included the first to file provision: "there is nothing inherent in a first-to-file system that will deter inventors from making use of their inventions as trade secrets and then some time later filing a patent application for the invention. *Thus, the maintenance* of the "public use" and "on sale" definitions of prior art *are needed to prevent such activity*." H. Rep. 110–314, 110th Cong. 1st Sess. (Sep. 4, 2007) at 57 (emphasis added). In fact, by expanding the prior user rights in 35 U.S.C. § 273, the AIA *further reduces* the risk for those engaged in such delay activity. These affirmative defense rights protect the commercial

user from patent infringement claims asserted by another inventor of the same subject matter if the commercial use commenced at least 1 year before the filing of the asserted patent's application.

In *City of Elizabeth*, this Court held that testing an inventive pavement for "usefulness and durability" for six years on a public roadway constituted experimental use. 97 U.S. 126, 133-34. It applied the "experimental use" doctrine as an equitable exception to the patent forfeiture bar. This is part of the common law. There is no indication that in enacting the AIA, Congress intended to abandon the equitable rules that operate alongside the statutory patenting bar – "a statutory purpose to the contrary" is *not* evident. *Astoria*, 501 U.S. at 108. There is no evidence that Congress changed the balance of the equities or substituted any of the equitable factors so as to change the meaning of the terms "on sale" or "public use." Because the post-AIA statute uses the same terms and does not "speak directly to the question addressed by the common law," the old common law continues to apply.

CONCLUSION

For the foregoing reasons, the holding of the Federal Circuit below should be affirmed and this Court should clarify that the statutory meaning of the terms "on sale" and "public use" have not changed by the enactment of the AIA.

Respectfully submitted,

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16 OCTOBER 2018

No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., *ET AL.*,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* INTEL CORPORATION IN SUPPORT OF RESPONDENTS

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INTEREST OF *AMICI CURIAE*[1]

Cutting-edge innovation has been the defining feature of Intel's business for the last half-century. Intel is incorporated and headquartered in the United States, and is a world leader in the design and manufacturing of semiconductor products, including hardware and software products for networking, telecommunications, data-centric cloud computing, artificial intelligence, autonomous driving, and other applications. To this day, Intel's micro-processing inventions are found in a vast array of the world's computers, from everyday desktops and laptops to the infrastructure that forms the backbone of the modern digital economy. Intel has also been at the forefront of developing new solutions for processing, storing, and transferring data. As part of Intel's research and development, it has frequently collaborated with other technology companies, entering into distribution, supply, and other commercialization agreements.

Intel owns more than 32,000 U.S. patents, and obtained 3,726 U.S. patents in 2017 alone—the third highest total of any company according to the most recent report by the Intellectual Property Owners Association (IPO). Intel is also a frequent target of patent-infringement lawsuits, the majority of which

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[1] No one other than the undersigned authored this brief in whole or in part, and no counsel or party other than the undersigned made a monetary contribution to fund or intended to fund the preparation or submission of this brief. Both parties have consented to the filing of this brief.

have for many years been brought by non-practicing entities. In addition, Intel has chosen to protect numerous aspects of its ground-breaking technology not through patents but as trade secrets. Intel thus has extensive experience in the U.S. Patent and Trademark Office (PTO), in patent infringement litigation before and after the enactment of the America Invents Act (AIA), and in protecting its intellectual property through both public and non-public avenues. Intel is therefore well-positioned to assist the Court's consideration of the practical implications of the arguments in this case.

SUMMARY OF ARGUMENT

Petitioner and its supporting *amici*, including IPO, have argued that the Federal Circuit's interpretation of Section 102 of the AIA would discourage the very innovation that the U.S. patent system is designed to promote. Based on its own experience, Intel believes the realities of the marketplace are to the contrary. The Federal Circuit's long-standing interpretation of the on-sale bar has not stifled innovation—nor would it compel small businesses to forgo their innovative efforts.

Consistent with settled legal principles, the Federal Circuit held that when petitioner entered into a Supply and Purchase Agreement for the claimed invention—which had already been determined to work for its intended purpose—petitioner's own commercial activity started a one-year clock to file for a patent on that invention. It is not unreasonable to expect that patent applications on new inventions be filed within one year of the

date they were first commercialized. This period generally offers sufficient time to assess the commercial viability of an invention, evaluate whether to seek patent protection, and prepare and submit a patent application. And under current law, as exemplified by this Court's decision in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), that one-year clock does not even begin to run if the invention is still under development or the inventor is engaged in pre-commercial activity. The two-pronged *Pfaff* analysis already provides substantial guidance and protection for innovators, including those in the semiconductor field.

By contrast, petitioner's interpretation of Section 102 would upset the balance in the patent system that Congress has struck: encouraging early enrichment of the store of public knowledge, while providing sufficient time to develop, refine, and experiment with a particular technology before an inventor must file for a patent. , If the well-established equilibrium underlying the Federal Circuit's decision were discarded, it would have the perverse effect of encouraging companies to withhold their inventions from public disclosure for as long as possible, and to extend the statutory patent term through the strategic use of confidentiality agreements. That would not promote innovation; it would instead encourage "confidential" sales, late-filed patent applications, and unfair patent litigation claims against practicing technology companies.

In addition, petitioner's interpretation would improperly shift the focus of the on-sale bar from the product or method that is the subject of a

commercial agreement to the text of that agreement itself. That approach is problematic in the semiconductor marketplace, where innovations are often invisible to the consuming public, and where those innovations involve complex and multifaceted components that are not easily described in commercial agreements. The on-sale bar ensures that only novel inventions are eligible for patent protection; the novelty of an invention should not turn on whether it was described in detail in a contract for sale. Instead, as has long been the case under the Federal Circuit's interpretation, the product or method that is sold should be the primary focus of this novelty analysis.

ARGUMENT

I. THE FEDERAL CIRCUIT'S INTERPRETATION OF THE ON-SALE BAR DOES NOT DISCOURAGE INNOVATION, PARTICULARLY IN THE SEMICONDUCTOR INDUSTRY.

A. Section 102(a)(1) Retains the One-Year Grace Period for Sales of the Claimed Invention.

Prior to the enactment of the AIA, a patent could not be obtained on an invention if it was "on sale in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. § 102(b) (2006). Similarly, under the AIA, a patent cannot be obtained on a "claimed" invention if it was "on sale" prior to the effective filing date of a patent application claiming that invention, except

when that sale was made by the inventor "1 year or less before the effective filing date of the claimed invention." 35 U.S.C. §§ 102(a), 102(b)(1) (2011). This restriction on patentability has been referred to, both before and after the passage of the AIA, as the "on-sale bar." *See, e.g.*, Pet. Br. 6.

The AIA thus left a critical feature of the prior statutory scheme intact: when an inventor first sells a claimed invention, that sale starts a one-year clock. If the inventor does not then file a patent application covering that invention within one year of selling it, the inventor will not be able to obtain patent protection for it. Even sales of the exact invention that will later be claimed do not foreclose the possibility of obtaining a patent, so long as a patent application is filed within one year of the first sale. Petitioner and respondents agree that the AIA retains an on-sale bar. Thus, the only question is whether the AIA narrowed the types of commercial activities to which the on-sale bar previously applied. As discussed below, there is no policy-based reason to conclude that it did so.

B. The Practical Concerns of Petitioner and Supporting *Amici* are Exaggerated and Untethered to the Realities of the Marketplace.

Petitioner and supporting *amici* urge this Court to reverse the Federal Circuit's decision on policy grounds that do not reflect business realities. Petitioner contends that affirming the Federal Circuit's decision would discourage "collaborative work that leads to innovation," and "has the

'potential to chill deals'" that might lead to the development of new and important products. Pet. Br. 48–49 (citations omitted). Petitioner further contends that, by continuing to apply the on-sale bar as it has done so historically, the Federal Circuit would leave "companies such as petitioner" with "no choice" but to abandon their business because "they do not have the resources to develop and bring drugs to market on their own." Pet. Br. 48.

IPO echoes these concerns in its *amicus* brief, contending that "the practical reality of operations in the present global economy" is that "many complex innovations require arms-length collaboration with third parties to refine and bring those innovations to market." IPO Br. 3. In IPO's view, the Federal Circuit's interpretation of Section 102(a)(1) would discourage such collaborative arrangements. IPO argues that it is particularly critical for the semiconductor industry that the AIA be interpreted as petitioner suggests because of the "close working relationship . . . between chip manufacturers and semiconductor processing equipment suppliers." IPO Br. 5. In this "innovation ecosystem, chip manufacturers . . . focus on chip design," but "also develop new processing inventions to help achieve particular design features." IPO Br. 5. IPO contends that "purchase agreements for equipment that implements those new processing inventions could give rise to an on-sale bar under the Federal Circuit's current interpretation of the law," which in turn could frustrate the development of new innovations. IPO Br. 6.

Petitioner and IPO are incorrect. They overlook the protection and guidance that the current law already provides, incorrectly imply that the on-sale bar has created a highly constrained environment that discourages innovation, and overstate any new "uncertainty" that the Federal Circuit's interpretation of the AIA would create.

Under the current law, the on-sale bar starts the one-year grace period to file a patent application only if a two-part test is satisfied: an invention "that is ready for patenting" must be "the subject of a commercial offer for sale." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998). Both prongs of the *Pfaff* test provide ample protection and guidance that allow for innovative collaboration and development work. The "commercial offer for sale" prong of *Pfaff* provides extensive guidance on how to structure collaborative arrangements so as not to trigger the on-sale bar—indeed, it is far from a foregone conclusion that the sort of partnerships that IPO discusses would even qualify as "commercial offers for sale." Similarly, the "ready for patenting" prong of *Pfaff* specifically provides that even if there were a commercial sale of an invention, the on-sale bar would not be triggered if that invention remains in the development phase.

Moreover, even a "commercial sale" of an invention that was "ready for patenting" does not foreclose the possibility of patent protection; a patent application on that invention must, however, be filed within one year of the first sale. In Intel's experience, that one-year grace period is adequate to assess whether to move forward with patent prosecution. Indeed, all of Intel's extensive

innovation to date—which has resulted in tens of thousands of patents, often from collaborative efforts—took place under a regime that IPO and petitioner argue is so unconducive to collaborative innovation that it must have been discarded under the AIA. Any suggestion that participants in the semiconductor industry or similar fields would be forced to forgo innovative efforts under the Federal Circuit's interpretation of the AIA is directly at odds with Intel's experience and the pace of semiconductor innovation to the present day.

1. The Existing "Commercial Offer For Sale" Requirement Addresses Concerns About the Scope of the On-Sale Bar.

The "commercial offer for sale" requirement already substantially alleviates IPO's concerns about the effects of the on-sale bar on the semiconductor industry. IPO is correct that semiconductor companies often work with third-party suppliers to develop specialized machinery to fabricate new and innovative chips or integrated circuits. IPO Br. 5–6. But in Intel's experience, IPO overstates the concern that these arrangements "could give rise to an on-sale bar under the Federal Circuit's current interpretation of the law." (*Id.* at 6.)

"[W]hether an invention is the subject of a commercial offer for sale is . . . to be analyzed under the law of contracts." *Grp. One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001). Several factors influence whether an invention has been the subject of a "commercial offer for sale," including "the passage of title," "the confidential

nature of the transactions," and the existence and extent of any commercial marketing by "the inventor himself or a third party." *Meds. Co. v. Hospira, Inc.*, 827 F.3d 1363, 1372, 1376-77 (Fed. Cir. 2016). In the scenario IPO outlined, each of those factors would weigh against a finding of a commercial offer for sale—typically title is not formally transferred in such a scenario, the related agreements are confidential, and there is no marketing of the equipment or process used to fabricate the integrated circuits. While that does not guarantee that every such agreement will avoid triggering the one-year grace period, current caselaw offers valuable guidance that allows companies like Intel to carefully tailor their arrangements with equipment manufacturers to reduce the likelihood of doing so.

In addition, to the extent that Intel and others in the semiconductor marketplace develop specialized machinery for integrated circuit fabrication or related processing inventions, those innovations may be protected not by pursuing patents, but as trade secrets. When an invention, such as a manufacturing process or a specialized piece of equipment, cannot easily be reverse-engineered, then it is often preferable to protect that asset or method as a trade secret. Under those circumstances, the on-sale bar is of no concern, because patent protection is less desirable than utilizing other forms of intellectual property, including trade secrets (that have no public disclosure obligations or fixed lifespan).

That stands in sharp contrast to other types of inventions, such as Intel's integrated circuits, as well

as the pharmaceutical products at issue in this case. For those products, widespread public use and commercialization is the ultimate goal, and thus trade secret protection may not be a viable long-term option. These practical realities allow companies in the semiconductor field to tailor their intellectual property and commercialization strategies. It is not necessary to alter the longstanding Federal Circuit approach in order for the on-sale bar to adequately protect the sort of innovations that IPO describes.

2. The "Ready for Patenting" Prong of *Pfaff* Adequately Protects Innovation.

Similarly, the "ready for patenting" requirement blunts any purported adverse effects of the Federal Circuit's decision. IPO contends that "third party sales and collaboration . . . are becoming ever more important across an increasing number of industries" and that under the Federal Circuit's interpretation of Section 102, inventors might not have the "necessary resources to fully refine an invention." IPO Br. 6–7. While IPO is correct that third-party sales and collaboration are important, particularly in the semiconductor industry, IPO overlooks how the "ready for patenting" prong of the current analysis already protects this development from triggering the on-sale bar.

As noted above, the second prong of the *Pfaff* test asks whether an invention that was the subject of a commercial offer for sale is "ready for patenting"; if it is not, then the one-year clock for filing a patent application does not begin to run. 525 U.S. at 67. An invention is "ready for patenting" if it has been

reduced to practice or if the inventor "prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." *Id.* at 67-68.

There is no question that the "ready for patenting" requirement of *Pfaff* will remain in place regardless of the outcome here. *See, e.g.*, Pet. App. 180a-181a ("The parties agree that the 'ready for patenting' prong under *Pfaff* has remained unchanged by the AIA."); Pet. Br. 30 (asserting that Congress "decided to retain 'on sale' as a discrete category of prior art," in part because that "preserves the substantial body of law on other aspects of the on-sale bar").

Accordingly, if commercialization begins relatively early in the development of the product, then the invention is likely not "ready for patenting," and the on-sale bar would not apply. *See, e.g.*, *Pfaff*, 525 U.S. at 68 n.14 (noting that an invention is not "ready for patenting" when there is "additional development after the offer for sale"); *Honeywell Int'l Inc. v. Hamilton Sunstrand Corp.*, 370 F.3d 1131, 1145 (Fed. Cir. 2004) (affirming jury determination that invention was not "ready for patenting" as of sale date despite evidence of contemporaneous drawings that were substantially identical to those that would later appear in the patent application); *Space Sys./Loral, Inc. v. Lockheed Martin Corp.*, 271 F.3d 1076, 1079 (Fed. Cir. 2001) (reversing district court's conclusion that invention was "ready for patenting" based on an engineering proposal, because "it was not until many months later, after

development and testing of an engineering model, that [it was] determined that the idea would work").

For those in the semiconductor industry working with collaborators to develop new integrated circuits or other innovations, it may take years before their invention is determined to work for its intended purpose. In Intel's experience, such efforts have not been and would not be impeded by the Federal Circuit's current interpretation of the on-sale bar. *See, e.g.*, *Keystone Retaining Wall Sys., Inc. v. Westrock Inc.*, 997 F.2d 1444, 1452 (Fed. Cir. 1993) ("If the inventor had merely a conception or was working towards development of that conception, it can be said there is not yet any 'invention' which could be placed on sale." (citations omitted)).

On the other hand, if an invention is far enough along in the development path to be "ready for patenting," then typically a patent would be filed within the one-year grace period. Here, the Federal Circuit found "overwhelming" evidence that the claimed invention was ready for patenting years before the first patent application was filed—a finding that petitioner does not challenge before this Court. Pet. 13 n.3; *see also* Pet. App. 47a-51a. Indeed, the Federal Circuit found consistent evidence that the invention here "worked for its intended purpose, from the final report for the 1995 Phase II trial to the preliminary results in January 2002 from a Phase III trial." Pet. App. 51a. That evidence included statements from the inventors that they possessed "the claimed invention, *i.e.*, 'a pharmaceutically stable solution for reducing emesis or reducing the likelihood of emesis'" in 1999—

approximately four years before a patent application on this invention was filed. Pet. App. 50a.

The settled interpretation of the on-sale bar need not be altered to promote experimentation and refinement of inventions, even those requiring commercial agreements to bring them to fruition. If such agreements are executed when the invention is not yet fully developed, then the one-year grace period does not even start to run. And if the invention is fully developed at the time it is first commercialized, then the inventor has a year to file a patent application. In Intel's experience, this offers an adequate period to determine the commercial viability of an invention, assess whether it is best protected through patents, trade secrets, or some other intellectual property, and prepare and file the initial patent documents. For decades, companies like Intel have been able to comply with these rules without halting or slowing U.S. innovation.

3. Petitioner and IPO Posit a False Dichotomy—Those in the Marketplace Do Not Face a Choice Between Commercialization and Patenting.

Petitioner asserts that companies will often "enter into development partnerships to share risk and defray cost." Pet. Br. 48. That is certainly true in Intel's experience. Petitioner also asserts that these partnerships are sometimes the only way for small companies to develop and bring their inventions to market. *Id.* That may also be true. But those assertions do not establish that the

longstanding interpretation of the on-sale bar is flawed.

Indeed, the Federal Circuit's precedent already accounts for these business realities. "Generally cost defrayal arrangements between collaborators are not deemed to be invalidating sales, nor are payments for use substantially for test purposes." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1356 (Fed. Cir. 1998); *see also Cont'l Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269, (Fed. Cir. 1991) (joint development between Coca-Cola and potential bottle supplier did not start the on-sale clock under Section 102). Under the existing on-sale construct, both smaller companies like petitioner and larger companies like Intel can enter into cost-defrayal agreements and development partnerships in hopes of commercializing an invention in the future. Even if the details of those agreements become public, and even if they are entered into after an invention has been fully developed, a patent may still be granted on the claimed invention, provided that the patent application is filed within one year.

4. Petitioner's Concerns About Uncertainty from the Affirmance of Longstanding Law Are Overstated.

Petitioner asserts that "for patents to stimulate innovation, their owners must be able reliably to predict their strength." Pet. Br. 47. Intel agrees. But petitioner also asserts that "the Federal Circuit's decision in this case . . . makes a mockery of that interest" because it will "potentially expose patentees to discovery-intensive inquiries into any

contacts and communications with third parties regarding the invention—not just in the United States but anywhere in the world." *Id.* Intel respectfully disagrees for several reasons.

First, when it comes to agreements like those petitioner executed, no "discovery-intensive inquiries" would be necessary, because petitioner obviously is aware of its own agreements. Indeed, petitioner affirmatively publicized the commercialization agreements relating to its claimed invention, announcing them "in a joint press release." Pet. App. 23a. In addition, all patent applicants have "a duty of candor and good faith in dealing with the [PTO], which includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability." 37 C.F.R. § 1.56(a). This duty of disclosure extends not merely to patents and publications, but also to "possible prior public uses, sales, offers to sell, derived knowledge, prior invention by another, inventorship conflicts, litigation statements, and the like." Manual of Patent Examining Procedure § 2001.04 (2018). Thus, when it comes to the inventor's own disclosures, like those that were alleged to have triggered the on-sale bar in this case, the Federal Circuit's interpretation of the AIA imposes no burden beyond existing PTO rules.

Second, the Federal Circuit's current approach to the on-sale bar is unlikely to create any additional uncertainty beyond that which would be part of the Section 102 analysis under petitioner's interpretation. Current sales outside of the United States may create an on-sale bar for a patent—that

will be the case regardless of the outcome here. But the possibility that a secret third-party foreign sale is the only disclosure that renders an invention unpatentable is relatively limited, particularly because over the course of at least the last three decades, the on-sale bar has almost always been triggered by sales by the patentee itself. *See, e.g.*, *Pfaff*, 525 U.S. at 57-58 (analyzing whether the commercialization activities of the inventor himself triggered the on-sale bar); *Energy Heating, LLC v. Heat On-The-Fly, LLC*, 889 F.3d 1291, 1300 (Fed. Cir. 2018) (concluding that dozens of prior commercial sales of fracking method by the inventor triggered the on-sale bar); *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147-48 (Fed. Cir. 1983) (analyzing whether the prior sales of the inventor triggered the on-sale bar).

Third, a patent applicant is in control of how to frame a patent application, just as that applicant is in control of the terms of any commercialization contract. The applicant can phrase its claims so as to capture elements of the invention that were not on sale, and can structure its collaboration agreements to avoid the finding that the later-claimed invention was subject to a commercial offer for sale.

II. PETITIONER'S INTERPRETATION OF SECTION 102 OF THE AIA WOULD UNDERMINE FUNDAMENTAL PRINCIPLES OF PATENT LAW.

A. Confidentiality Agreements Could Be Strategically Used to Avoid Triggering the On-Sale Bar.

Petitioner's position would offer opportunities for companies to improperly extend the statutory term of patent protection through strategic use of confidentiality agreements. Petitioner notes that the "basic *quid pro quo* of patent law" provides that an inventor gives the public a useful invention and gets a monopoly in exchange. Pet. Br. 46. While that is generally true, the *quid pro quo* is more specific than that: in exchange for public disclosure of an invention, **a 20-year patent term** is granted from the date of filing. Petitioner's interpretation of Section 102 of the AIA offers a perverse incentive for companies to treat all of their inventions as trade secrets in the initial instance, and then leave the door open to file for a patent later so that the 20-year term could be extended.

For instance, those in the semiconductor industry could enter into non-disclosure agreements with their manufacturers and distributors, allowing for commercialization of new innovations without disclosing any of the elements of those inventions to the public. The invention would thus be classified as confidential or as a trade secret. At the first sign of competition for that invention, or after several years of commercial effort had been completed, the

inventor could then "lift the veil" of secrecy on the invention, file for patent protection, and enjoy more than 20 years of marketplace exclusivity on that invention. That is at odds with the fundamental principles that underlie the on-sale bar. *See, e.g.*, *Pfaff*, 525 U.S. at 64 (noting that the on-sale bar serves as a check that "confin[es] the duration of the [patent] monopoly to the statutory term"); *see also C.R. Bard Inc.*, 157 F.3d at 1357 ("A primary policy served by the on-sale bar is to provide time for an inventor to determine the reception of his invention in the marketplace before entering into the patent system, while the one-year limit prevents undue lengthening of the period of exclusivity.").

Indeed, the likeliest outcome of petitioner's interpretation of the on-sale bar would merely be the proliferation of confidentiality and non-disclosure agreements in the semiconductor and other industries. These agreements are already frequently used, but would likely become more common, as inventions that would otherwise be deemed to have been effectively commercialized would be technically protected by confidentiality agreements. An invention that had been "confidentially" sold for years could be patented, even though the enrichment of the store of public knowledge would have been substantially delayed. That does not serve the constitutional interests of the patent system.

B. Petitioner's Interpretation Would Encourage Delays In Filing for Patents.

Petitioner does not dispute that it had an invention that was ready for patenting for nearly a

decade before it first applied for a patent on it. Were petitioner to prevail, it would be the only entity able to exploit the claimed invention for nearly three decades. This is highly problematic. "The on-sale bar of § 102(b) represents a balance of the policies of allowing the inventor a reasonable amount of time to ascertain the commercial value of an invention, while requiring prompt entry into the patent system after sales activity has begun." *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 98 F.3d 1318, 1322 (Fed. Cir. 1996).

Petitioner and supporting *amici* argue that the first-to-file system provides adequate incentives for prompt filing of patent applications, rendering the additional incentives of the one-year grace period for sales unnecessary. Pet. Br. 16 (asserting that "it is unnecessary for the on-sale bar to provide inventors with an additional incentive to enter the patent system promptly").) That argument misses the mark for two reasons. First, if the first-to-file system inherently provided all the incentive needed for prompt filing, then the one-year grace period would be unnecessary; yet, Congress retained it in Section 102(b) of the AIA. Second, in Intel's experience, the highly specialized and cost-intensive nature of its innovations means that it is unlikely that other companies are simultaneously working on precisely the same innovation. In other words, while there are certainly technological "races" among competitors, those innovations are unlikely to overlap precisely. Absent the one-year deadline to file a patent, those in the semiconductor marketplace could delay their

application filing dates in an attempt to extend their patent monopoly.

C. Petitioner's Interpretation Wrongly Shifts Focus To The Text of Commercial Agreements, And Ignores Their Subject Inventions.

Finally, petitioner and its supporting *amici* would improperly shift the focus of the on-sale analysis from the actual elements of the commercialized device or method to the text of the commercial agreement—a result Congress is unlikely to have intended. They argue that the on-sale bar should not apply to confidential commercial sales agreements unless those agreements disclose the details of the subject invention. Petitioner highlights the fact that the "proposed formulation" of the later-claimed dose of palonosetron was redacted from publicly disclosed documents. Pet. Br. 10. IPO similarly argues that "*agreements* that do not disclose the claimed invention do not bar patentability or invalidate patent claims because the invention claimed has not [been] 'made available to the public.'" IPO Br. 21 (emphasis added). But the application of the on-sale bar should not depend on whether a commercial contract itself functions as a fully enabling disclosure of the claimed invention; the on-sale analysis should focus where it always has: on whether the product or method that is the subject of that agreement embodies each aspect of the claimed invention. If Congress had really intended to depart so radically from the longstanding focus of the on-sale analysis, it surely would have done so by inserting clear statutory

language to this effect. Neither petitioner nor IPO points to any such language.

Section 102(a) of the AIA addresses the question of patent "novelty," and enumerates several categories of "prior art" that render a claimed invention unpatentable. Only two of those categories ("patented," and "described in a printed publication") require that a writing be analyzed to determine whether it discloses the later-claimed invention. 35 U.S.C. § 102(a) (2011). Section 102(a) does not require that a claimed invention be "described in a sales contract"; it merely requires that the "claimed invention" be on sale. *Id.* The plain language of this statute thus focuses the on-sale analysis on the product or method that is allegedly on sale, not on the sales contract. *See, e.g.*, *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1353 (Fed. Cir. 2002) (holding that "the assessment of whether a device sold was an embodiment of a claimed invention [is] 'the first determination' in the on-sale bar analysis" (citation omitted)).

An invention-focused inquiry is not only consistent with the statutory language, but also accounts for the multifaceted nature of many innovations. In the pharmaceutical context, it may be possible to concisely describe the entire claimed invention in an agreement (as was the case here). But for many inventions—including in the semiconductor field—it would be impractical to fully describe the subject device or method in a related sales agreement. For instance, individual semiconductor products can embody thousands of

discrete innovations, many of them infinitesimally small, unadvertised, and not readily apparent to the public. Such products are often identified solely by a shorthand name or product number in related commercial agreements, which themselves typically offer no detail on the specific innovations embodied in that product. Petitioner's interpretation of Section 102(a) would require that a sale be accompanied by a written description of any later-claimed features in order to trigger an on-sale bar. That interpretation finds no support in the AIA, is impractical if not impossible to achieve in many contexts, and would insulate many innovations that are not easily described in sales contracts from novelty-defeating prior art (thus allowing for potential extension of the patent term beyond its statutory maximum).

That is not to say that the text of commercial agreements relating to a later-claimed invention is irrelevant to the on-sale analysis. On the contrary, as discussed above, the terms of that agreement should be analyzed to determine whether it has the hallmarks of a commercial sale. But the on-sale bar has not been limited only to those commercial contracts that recite each and every element of the claimed invention. Nor would the policies of the patent laws be advanced by limiting the on-sale bar in that manner.

CONCLUSION

For the foregoing reasons, *amicus* respectfully urges the Court to affirm the decision by the Court of Appeals for the Federal Circuit.

Respectfully submitted,

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OCTOBER 16, 2018

No. 17-1229

In the
Supreme Court of the United States

HELSINN HEALTHCARE S.A.,
Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF

THE INTELLECTUAL PROPERTY LAW ASSOCIATION OF CHICAGO

AS *AMICUS CURIAE*

IN SUPPORT OF NEITHER PETITIONER NOR RESPONDENTS

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AAU letter	Letter, Association of American Universities et al. to attn.: Mary C. Till, Sr. Leg. Advisor, Office of Pat. Leg. Admin., Office of Dep. Comm. For Pat. Ex. Policy, October 5, 2012 ("AAU letter")
AIA	America Invents Act
AIA, Hearing	America Invents Act, *Hearing before the Subcommittee on Intellectual Property, Competition, and the Internet of the Committee on the Judiciary House of Representatives*, 112th Cong. 65 (2011)
A Patent System for the 21st Century	Stephen A. Merrill, et al, *A Patent System for the 21st Century*, National Academy of Sciences (2004)
Armitage	Robert A. Armitage
ABA-IPL	American Bar Association Section of Intellectual Property Law
AIPLA	American Intellectual Property Law Association
Harmonization Hearing	*The Patent System Harmonization Act of 1992: Joint Hearing on S. 2605 and H.R. 4978 Before the S. Comm. on the Judiciary and the Subcomm. on Intellectual Property*

	and Judicial Administration of the H. Comm. on the Judiciary, 102nd Cong. (1992)
Helsinn	*Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017)
House	House of Representatives
Individual Academics Brief	Brief of Amici Curiae 42 Intellectual Property Professors, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017)
IP	Intellectual property
IPLAC	The Intellectual Property Law Association of Chicago
Lilly	Eli Lilly & Company
Manzo	E. Manzo, *The America Invents Act: A Guide to Patent Litigation & Patent Procedure*, Thomson Reuters (Nov. 2013)
NAM	National Association of Manufacturers
Organizations	The "[n]umerous organizations, institutions, and companies [who] advocated [that] the U.S. adopt a first to file [patent] system." Sen.

	Rep. No. 111-18.
Perspectives Hearing	*Perspectives on Patents, Hearing before the Subcomm. on Intellectual Property of the Comm. on the Judiciary*, United States Senate, S. Hrg. 109-983 (2005)
USCO	United States Copyright Office
USPTO	United States Patent and Trademark Office

INTEREST OF *AMICUS CURIAE*

The Intellectual Property Law Association of Chicago ("IPLAC") submits this brief as *amicus curiae*, but in support of neither party on the ultimate merits of the case.[1, 2, 3] IPLAC has as its governing objects, *inter alia*, to aid in the development of intellectual property ("IP") laws, the administration of them, and the procedures of the U.S. Patent and Trademark Office ("USPTO"), the U.S. Copyright Office ("USCO"), and the U.S. courts and other officers and tribunals charged with

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[1] Pursuant to Supreme Court Rule 37.6, no counsel for a party authored this brief in whole or in part, no such counsel or a party made a monetary contribution intended to fund the preparation or submission of the brief, and no person other than the *amicus curiae*, its members, or its counsel, made such a monetary contribution to the preparation or submission of the brief.

[2] In addition to the required statement of footnote 1, IPLAC adds that after reasonable investigation, IPLAC believes that (a) no member of its Board or Amicus Committee who voted to prepare this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter, (b) no representative of any party to this litigation participated in the authorship of this brief, and (c) no one other than IPLAC, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

[3] Pursuant to Supreme Court Rule 37.3(a), IPLAC has obtained the consent of the parties to file this amicus brief. Petitioner has filed a blanket consent letter with the Court, and Respondent has given IPLAC individual consent.

administration. IPLAC was founded in 1884 as The Patent Law Association, making it by rich history the country's oldest bar association devoted exclusively to intellectual property matters. It was dedicated on founding to "making more definite, uniform and convenient" the laws and rules of IP practice. Today, IPLAC is an association of over 1,000 members of the legal profession of the United States in good standing with interests in the laws of IP, licensed to practice in any state or the USPTO, including Chicago-local and non-local attorney members, judiciary members, and faculty members; patent agents, paralegal members, and student members. IPLAC members have their IP law interests in the areas of patents, trademarks, copyrights, trade secrets, social media, advertising, blockchain, data protection, outsourcing, privacy, and top level domains. Some members are in private and corporate practices and appear before federal courts throughout the United States, as well as the USPTO and USCO. Members represent both rights holders and other actors in roughly equal measure, and in litigation, are split roughly equally between plaintiffs and defendants. IPLAC is centered in Chicago, a principal locus and forum for the nation's authors, artists, inventors, scholarly pursuits, arts, creativity, research and development, innovation, IP creation, IP litigation, and IP awareness.

SUMMARY OF ARGUMENT

AIA §102(a)(1) has a specific structure, content, and meaning by virtue of having two "or's," an "otherwise," and an adjective "claimed" before its subject "invention." The specific meaning of AIA

§102(a)(1), after a careful analysis of the placement and meaning of these terms, is that a patent cannot issue where a claimed invention has been the subject of a patent, a printed publication, or in the alternative to patents and publications, the subject of an event that has made the claimed invention available to the public, such as a public use that makes it available to the public, an on sale that does the same, or an event that any way or manner other than an availing use or on sale makes it available to the public.

The essence of the Federal Circuit panel's *Helsinn* decision under review is its conclusion that for an invention subject to the AIA, once the existence of an inventor's terms of a sale, if any, are publicly known, and the sale is to be of the invention, then the invention is legally publicly known, even though the invention is not factually publicly known. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017) , Pet. App. at 43a. Colloquially, the essence of the decision is that if the public were to know that an inventor was trying to sell an invention, and what his terms were, even if the public did not know what the invention was, the public's knowledge of the attempt to sell would itself be prior art to a later patent on the invention (one filed after a year from the knowledge).

This is a mistake as in *Pfaff v. Wells*, 525 U.S. 55 (1998), and an utterly odd conclusion for the specific structure, content, and meaning of AIA §102(a)(1), one against assessing the public availability of what §102(a)(1) focuses on, a "claimed invention," by express wording. As happened in

Pfaff, the Federal Circuit has made an on sale decision by wrongly focusing on a matter that is completely absent from the relevant text of §102. *Compare Pfaff*, 525 U.S. at 60, 66-68 (pre-AIA §102 text did not reference "substantial completion," which was the focus of the Federal Circuit decision reversed in *Pfaff*).

The numerous organizations, institutions, companies, and their representatives, driven by the 21st century needs of the country, who caused the U.S. to adopt a first-inventor-to-file patent system, accomplished the opposite of the Federal Circuit panel's decision. Their drive for patent reform and a first-inventor-to-file system began as early as the 1980s. From the beginning, they strove for simplicity, transparency, objectivity, and predictability in the patent law, and specifically within their efforts, for the curtailment and elimination of "secret prior art" from being patent-defeating prior art in their proposed first-inventor-to-file system. Their reasons were the fit of the elimination with simplicity, transparency, objectivity, and predictability. Congress passed the AIA in response to these organizations' efforts. And as early as 2007-2009, in the Reports by which the Patent Reform Acts of 2007 and 2009 introduced the AIA language of §102(a)(1)—the Acts of 2007 and 2009 were the AIA's direct predecessors—Congress informed the advocating organizations and the world at large that the coming new §102(a)(1) would have "the phrase 'available to the public' ... to emphasize the fact that [the claimed invention] must be publicly available [for it to be prior art to later attempts to patent it]." *See infra* at 9-10.

The USPTO participated in Congressional efforts to fashion and pass the Patent Reform Acts of 2007 and 2009, and the AIA, at the request of Congress, and was unquestionably aware of matters such as the two Reports' introductory explanations of the potential AIA's contents. So when, just after the passage of AIA, the USPTO informed the numerous organizations whose dedicated efforts drove the country to the AIA that the "AIA does not include the pre-AIA use of secret sales as prior art," the USPTO no doubt knew what it knew, correctly stated what it knew, and the organizations no doubt knew that the USPTO was correct in its statements. *See infra* at 14-16.

A principal representative for the organizations in patent reform, and advocate for the AIA in his own right, Robert Armitage, who spoke for the National Association of Manufacturers ("NAM"), the American Intellectual Property Law Association ("AIPLA"), the American Bar Association ("ABA"), and Eli Lilly & Company ("Lilly"), also assured the organizations *and assured Congress itself* further that "secret sales" were "not ... prior art," in authoritative explanations. *See infra* at 12-14.

Nothing in the AIA, which embodied Congress's overhaul of past patent prior art law to give the U.S. a first-inventor-to-file system, one with simplicity, transparency, objectivity, and predictability, justified the Federal Circuit panel's improper change of focus. To determine prior art, away from the matter of the public availability of a claimed invention, and instead to the matter of

whether there was public knowledge of an inventor's terms of sale, is wrong.

Regressive manufacture of worried ideas over the specifics of the text of AIA §102(a) relative to this Court's guidelines for statutory construction, mostly in the form of a parade of potential horribles for future burdens on academics and the courts to learn new law, is what has caused a dispute over the meaning of AIA §102(a)(1). But the potential horribles do not change the specific structure, content, and meaning of AIA §102(a)(1), or its history and background as known to Congress, the USPTO, dedicated and altruistic—even patriotic—organizations, and the mavens of the patent reform that provided the AIA. AIA prior art law has a sole focus on the public availability of a claimed invention itself, not an inventor's terms of sale in relation to any related invention, because of the need for consistent, universal focus on simplicity, transparency, objectivity, and predictability for patent matters in the 21st century.

The Federal Circuit panel was wrong to make it otherwise. It was wrong to misdirect itself as it did in *Pfaff*. It was wrong to snatch from Congress, the USPTO, patent reform organizations, their leaders, and the country as a whole, some of the bold, streamlining patent reform that the AIA accomplished.

STATEMENT OF FACTS

An effort of patent reform that led to the AIA, including a first-inventor-to-file patent system, began in at least one quarter as early as 1982. In

that quarter, it began with Robert Armitage. *See* Robert A. Armitage, *Reform of the Law on Interference: A New Role for an Ancient Institution in the Context of a First-to-File System*, 64 J. Pat. Off. Soc'y 663 (1982). Mr. Armitage testified before Congress in 1992 representing NAM, in part toward adoption of a first-inventor-to-file patent system and curtailment of the on sale bar to patents. *See The Patent System Harmonization Act of 1992: Joint Hearing on S. 2605 and H.R. 4978 Before the S. Comm. on the Judiciary and the Subcomm. on Intellectual Property and Judicial Administration of the H. Comm. on the Judiciary*, 102nd Cong. 186-97 (1992) ("Harmonization Hearing").

Major patent reform of the types in the AIA stalled for many early years and then, with new empirical analysis, new study, and new sharing of information, reform broke forth into a striking, new period for change. A 2004 study was released by the National Academy of Sciences ("NAS"). *See Perspectives on Patents, Hearing before the Subcommittee on Intellectual Property of the Committee on the Judiciary*, United States Senate, S. Hrg. 109-983 (2005) at 2 (new Subcommittee), 12, 24, 39, 48-49, 69, 78, 121-26, 144 (consensus) ("Perspectives Hearing"). A 2005 empirical analysis was published, with a foreword by Mr. Armitage, *id.* at 72-92, 137-145; *see also* Stephen A. Merrill, et al, *A Patent System for the 21st Century*, NAS 124-27 (2004) (consensus) ("A Patent System for the 21st Century"). A nationwide consensus rapidly developed in the patent community for the patent system to move to a first-inventor-to-file patent system. Perspectives Hearing at 30-33, 44-71. Also in 2005,

the Senate created an Intellectual Property Subcommittee of the Senate Judiciary Committee. Mr. Armitage was there as a witness to explain the new consensus.

Congress through Subcommittee Chairman Senator Hatch specifically asked the USPTO, which was present at the first hearing of the new subcommittee, to work with Congress as it fashioned patent reform legislation. *Id* at 17. Robert Armitage from the 1982 article and the Harmonization and Perspectives Hearings was already a recognized "veteran" in Congressional patent matters, *id.* at 3, a representative of NAM and Lilly in testimony, *id.* at 30-32, 44-71, a past President of the AIPLA, *id.* at 118, and co-chair of an AIPLA Special Committee on Patent Legislative Strategies, *id.* This AIPLA Special Committee developed patent reform proposals which were approved by the AIPLA Board of Directors and were explained in town hall forums across the country jointly sponsored by the Federal Trade Commission, NAS, and AIPLA. *Id.* at 117-18.

AIPLA proposed to Congress, and Lilly through Mr. Armitage endorsed, both first-inventor-to-file and "eliminating the so-called 'forfeiture' aspect of the current patent law that prevents inventors (and only the inventors) from patenting subject matter that they themselves have placed or caused to be placed into non-public commercial use or made the subject of non-public offers for sale." *Id.* at 51 n. 2. A Patent System for the 21st Century, at 124, had advocated harmonizing "rules of prior art" internationally.

Reform efforts continued over several years, in both the Senate and House. For instance, a Patent Reform Act of 2007, Senate bill 1145, introduced in a Senate Report 110-259, created a first-inventor-to-file system. This 2007 Report cited the "[n]umerous organizations, institutions, and companies" that were advocating for this system, and indicated an appearance of the USPTO in the proceedings. Senate Report 110-259 at 7 n. 24. The 2007 Report stated the Act "necessarily, modifie[d] the prior art sections of the patent law." *Id.* at 9. The 2007 Report stated as to §102 that "the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, and to emphasize that it [i.e., anything to be considered to be prior art] must be publicly available." *Id.*; E. Manzo, *The America Invents Act: A Guide to Patent Litigation & Patent Procedure*, Thomson Reuters (Nov. 2013) at 17.

The Patent Reform Act of 2009 introduced in the Senate in a Report 111-18, continued the first-inventor-to-file system of the Patent Reform Act of 2007, and again cited the "[n]umerous organizations, institutions, and companies" that were advocating for this system. 2009 Senate Report 111-18 at 3, 32, 41. The 2009 Report again stated the Act "necessarily, modifie[d] the prior art sections of the patent law." *Id.* at 6. The 2009 Report again stated as to §102 that "the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize that it [i.e., anything considered to be prior art] must be publicly available." *Id.*; *see also id.* at 32, 70; Manzo at 11.

The USPTO regularly participated in Congressional patent reform efforts, with its Director appearing and testifying multiple times. *See* 2009 Senate Report at 5 ns. 14-18.

The AIPLA compared the 2009 House and Senate bills and stated it "support[ed] amending section 102 to limit patent defeating prior art to information which is publicly accessible." AIPLA, *Summary and Comparison of H.R. 1260 and S. 515, the Patent Reform Acts of 2009*, at 1.[4]

Reform was not being limited to first-inventor-to-file and redefining prior art. *Id.* Proposals ranged across matters of derivation proceedings, inventor's oaths, assignee filing, damages, willful infringement, prior user rights, reexamination, post-grant opposition, a Patent Trial and Appeals Board, a study and report on reexamination, publication of patent applications, third party submissions of prior art, venue for patent infringement cases, interlocutory appeals, USPTO fee setting authority and a variety of additional matters to a total of thirty-one distinct potential areas of reform. *Id.*

A 2011 Senate amendment made the act in the Senate at that time the "America Invents Act." *See* J. Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 Fed. Cir. B.J. 435, 445 (2012). A surprising and intense last-minute debate over first-inventor-to-file occurred. *Id.*

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[4] *See* http://www.aipla.org/Advocacy%20Shared%20Documents/PatentReformLegComparisonChart-050509.pdf

at 453-461. The Senate bill passed. The House considered the America Invents Act as H.R. 1249 in 2011. *See America Invents Act, Hearing before the Subcomm. on Intellectual Property, Competition, and the Internet of the Comm. on the Judiciary House of Representatives*, 112th Cong. 65 (2011) ("AIA Hearing"); *see also* Matal, 21 Fed. Cir. B.J. 461-464. The AIA in this hearing had the proposed §102 of the Patent Reform Acts of 2007 and 2009 in the Senate, and the §102 the AIA now has. AIA, Hearing at 4. The USPTO called first-inventor-to-file essential. *Id.* at 44. A witness reiterated that the AIA was to have "changes that bring objectivity to the determination of what information can be used to assess the patentability of an invention – patents, printed publications, or other publicly known information." *Id.* at 71. The House Report itself was confirming, that "[t]he Act simplifies how prior art is determined, provides more certainty, and reduces the cost associated with filing and litigating patents." The House passed the AIA, and then the Senate passed it as well. Matal, 21 Fed. Cir. B.J. at 464-466.

Reviewing the AIA the day after it passed the House and Senate, and well before its Presidential signing, Senator Leahy advised all involved that §102(a)(1) "was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art." He stated that patent-defeating prior art must meet the "the public accessibility standard that is well-settled in current law, especially case law of the Federal Circuit." 157 Cong.

Rec. S1496-S1497 (daily ed., March 9, 2011), (Statement of Sen. Leahy).

Also reviewing the changes of the AIA, Mr. Matal, Judiciary Committee Counsel to Senator Kyl, stated that "The new §102 ... sweeps away a large body of patent law. All the 'loss of right to patent' provisions of pre-AIA §102 have been repealed. ... The new subsection (a)(1): (1) incorporates pre-AIA §102(b)'s inclusion of the patent owner's own activities, including public commercialization of the invention ... In light of the AIA's repeal of all 'loss of right to patent' provisions based on secret activities from §102, those words have been removed from the title of §102. ..." Matal, 21 Fed. Cir. B.J. 450. He added as to §102 (a)(1) that it "allows a patent to issue unless there has been a 'public disclosure of prior art.' This prior art can come in any form that makes the invention publicly accessible." *Id.* at 451.

Mr. Armitage, patent veteran, witness in multiple appearances, past advocate for major patent reform and what became the AIA, for NAM, AIPLA, and Lilly, was by the time being referenced also Chair of the ABA Section of Intellectual Property Law ("ABA-IPL"). He reviewed AIA's changes, stating that with the AIA, "Congress completed a statutory patent revolution." R. Armitage, *Understanding the America Invents Act and its Implications for Patenting*, 40 AIPLA J. 1, 8 (2012) . He stated that inventions were patentable if the claimed invention was sufficiently different from "the prior art, which consists of—1) disclosures made available to the public (*i.e.*, subject matter publicly accessible)." *Id.* at 22 (item 2 not relevant)). He

continued, that understanding that prior art had to be publicly accessible was critical to understanding what the AIA created in a new patent system:

> Thus, by far, the provisions of the AIA that are of the utmost importance to realizing the benefits contemplated by the reforms are premised on the successful implementation of the new statutory definition for 'prior art.' Either this new definition will successfully translate into prior public disclosures, ... or it would be difficult to make sense of what Congress has done in the aggregate for patent law ...

Id. at 23.

As if that were not definitive enough on the subject, he continued that "a 'disclosure' is now the sole route by which subject matter qualifies as prior art." *Id.* at 29. He persuasively critiqued past "on sale" law as having a "bizarre defect" in forcing forfeiture of patent rights over inventor activities that were in secret. *Id.* at 42-43. He thoroughly explained that in the AIA, Congress "erase[d] each of the ancient 'loss of right to patent' provisions from pre-AIA §102." *Id.* at 45, also 50-51, 52. This was a "process of conscious subtraction," he said. *Id.* at 46. Indeed, he observed:

> [the] terms "in public use or on sale" have been further modified

> and qualified by a new phrase that reads in its entirety: "in public use, on sale, or otherwise available to the public." Congress employed this mechanism to impose an overarching requirement for availability to the public in order for a prior disclosure to constitute prior art. ... can the new language somehow read to allow secret uses or secret offers for sale or other secret or private acts, unavailable to the public, to impact patentability ...? There is abundant ground for confidence that the clarity of the new language will not be negated by the courts ... The overarching requirement for a disclosure to be "available to the public" has been placed into new §102(a)(1) in a manner making it virtually impossible to read it other than as an express repudiation of the Metallizing Engineering doctrine.[5]

Id. at 53-4.

Mr. Armitage drove his point home that secret on sale activity is not prior art under the AIA with repeated, effective blows that defy contradiction. In

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[5] *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946)

addition to the above, *see, e.g., id.* at 54-60 and especially n. 206 regarding sale activities and forfeiture.

Proved in the briefs of others, the USPTO adopted the positions of Congress, its members, and the advocating organizations and their representatives, most notably the spokesman and historian, Mr. Armitage. *See* references above; *see also ABA-IPL letter to David Kappos, Under Secretary of Commerce for Intellectual Property and Director of the USPTO*, November 17, 2011, at 2 on §102(a)(1).[6] Moreover, Mr. Armitage reported back to Congress about the USPTO implementation of the AIA. *See Statement of Robert A. Armitage, Senior Vice President and General Counsel, Eli Lilly & Company, Indianapolis, Indiana, before the United States House of Representatives Committee on the Judiciary on "Implementation of the Leahy-Smith America Invents Act,"* May 16, 2012. Mr. Armitage testified, again repeatedly, with reinforcement in the Matal and Leahy analyses referenced above, and in his own analyses, that the AIA ended forfeiture provisions in pre-AIA law, required public disclosure of the subject matter of patent claims for inventor actions before patent applications to cause prior art, and did so by "consensus position of the U.S. patent user community." *Id.* at 4-14 (consensus on 6). He urged that Congress "speak ... until no doubt exists as to the words it placed in the statute and the import and intent of those words." *Id.* at 14. He

[6] *See* https://www.uspto.gov/sites/default/files/patents/law/comments/x_aia-a_aba_20111117.pdf.

advocated that Congress have the USPTO adopt the positions of Congress—and the USPTO did.

Indeed, first the USPTO requested comments. In response, an association of 59 preeminent research universities, a council representing the presidents of 1,800 accredited universities, and four other associations representing similarly large and prestigious academic groups, stated that they had collaborated throughout the enactment of the AIA, knew there was an extensive body of pre-AIA case law, and yet that "non-public offers for sale should not be considered prior art precisely because they are not public." *Letter, Association of American Universities et al. to attn.: Mary C. Till, Sr. Leg. Advisor, Office of Pat. Leg. Admin., Office of Dep. Comm. For Pat. Ex. Policy*, October 5, 2012 ("AAU letter").[7]

Then, in educating the public to the AIA, the USPTO went out in "Road Shows," and informed everyone paying attention that the "AIA does not include the pre-AIA use of secret sales as prior art."[8] The patent user community has as a result, since these events, acted in reliance on the AIA eliminating secret sales as prior art.

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[7] *See* https://www.uspto.gov/patent/laws-and-regulationscomments-public/comments-examination-guidelines-implementing-first

[8] *See* https://www.uspto.gov/sites/default/files/aia_implementation/fitf_live_overview_training_slides-march2013.pdf at 13 slide 25.

Meanwhile, for patents not subject to the AIA, most pre-AIA law continued in effect.

ARGUMENT

I. AIA §102(a)(1) has a specific structure and content: two "or's," an "otherwise," and a "'claimed' invention" as its subject.

The starting point for this Court's efforts in this case is the text of AIA §102(a)(1). The text has a specific structure and content. It—unusually—has two "or's." It has an "otherwise." It has the adjective "claimed" before the word "invention" in its subject. Italicized at the referenced words, this is its structure and content:

> [A person shall be entitled to a patent unless -]
>
> (1) the *claimed* invention was patented, described in a printed publication, *or* in public use, on sale, *or otherwise* available to the public before the effective filing date of the claimed invention[.]

II. The specific structure and content of AIA §102(a)(1), *i.e.*, its two "or's," "otherwise," and "'claimed' invention," give it a specific meaning.

The cited two "or's," "otherwise," and "'claimed' invention" give AIA §102(a)(1) a specific meaning. The two "or's" start the point. The first "or" links the terms "patented" and "described in a printed publication" with each other and with the terms "in public use," "on sale," and "available to the public." The first "or" links to give AIA §102(a)(1) a first

alternative term "patented," a second alternative term "described in a printed publication," and a third alternative, a group of terms "in public use," "on sale," and "available to the public." The first term, second term, and group are themselves a group. The "group" "in public use," etc., is a subgroup.

The second "or" links the three alternative terms in the subgroup: "in public use," "on sale," and "available to the public."

With the effect of the two "or's" seen, the effect of the "otherwise" can be seen. The terms "in public use," "on sale," and "available to the public" are alternatives in a subgroup separated from the preceding two terms that are in parallel to the subgroup, *i.e.*, the terms "patented," and "described in a printed publication." The "otherwise," in the subgroup, not in position superior to being in the subgroup—not placed after the first "or"—further joins the terms "in public use," "on sale," and "available to the public," and does not affect the terms "patented" and "described in a printed publication." The "otherwise" has an effect on the terms of the group "in public use," "on sale," and "available to the public," that according to precedent, arises from two primary possible meanings for "otherwise:" "to the contrary," or "in a different way or manner." *See, e.g.*, *Marx v. General Revenue Corp.*, 568 U.S. 371 (2013)(compare the majority use of "to the contrary" with the minority use of "in a different way or manner").

The word "otherwise" in §102(a)(1) is to be understood to mean "in a different way or manner"

for one central reason. The terms "in public use" and "on sale," to their primary purpose, are terms consistent with pre-AIA case law—unless modified in §102(a)(1), which they are, as will be seen—*i.e.*, they are terms that could reflect events that made inventions "available to the public." "Public use," pre-AIA, could in some cases be private, but for the most part public uses were public. "On sale" could be the same. Thus, reading "otherwise" to mean "to the contrary" makes no sense. Reading it so would take the position that in no past cases have the terms "in public use" and "on sale" related to events that made inventions "available to the public." But in many and most past cases they had so related.

Since the word "otherwise" cannot sensibly mean "to the contrary," the word "otherwise" means "in a different way or manner." With "otherwise" interpreted, the subgroup of terms in §102(a)(1) reads "in public use, on sale, or in a different way or manner available to the public." The modification "otherwise" makes "in public use," "on sale," and "available to the public" three alternatives in their subgroup *of a kind* with each other and with only a different way or manner to them: it makes them alternatives of a kind in that in some way or manner they are events that make an invention "available to the public."

The adjective "claimed" in the subject "claimed invention" completes the specific structure and content of §102(a)(1) for this case's needs. It is a "claimed" invention and not some other invention that is the subject. For example, a claimed process, and not a product of the process, is the subject of

§102(a)(1). Since the patent to be issued on the "claimed invention" does not exist at the time that is the subject of §102(a)(1), neither does the claim to the invention; attention is required to a future patent's claims, not some loose thought of what was "the invention" in any aspect, claimed or unclaimed. For example, attention is required to a claimed process, not the product of the process, which might but for the term "'claimed' invention" have been considered an aspect of the subject invention. Attention is required to the claimed invention, not an accompanying or "companion" invention, especially not one unclaimed.

The specific subject of AIA §102(a)(1), as can be seen after this analysis, is whether a claimed invention—not any invention, not a companion invention, a product of invention, or an aspect of invention—has been the subject of a patent, a printed publication, or in the alternative to patents and publications, the subject of any way or manner of the making of public availability, such as a public use that makes the claimed invention available to the public, an on sale that makes the claimed invention available to the public, or any other way or manner that makes the claimed invention available to the public. To interpret §102(a)(1) differently would require that its specific structure and content be ignored.

III. The legislative history thoroughly and consistently affirms the structure, content, and meaning of AIA §102(a)(1).

There can be no doubt that "[n]umerous organizations, institutions, and companies ...

advocated [that] the U.S. adopt a first to file [patent] system." *See infra* Statement of Facts. The AIA exists because all these organizations, institutions and companies ("organizations") caused the AIA to come into existence. NAS issued a compelling report, the organizations developed consensus, and all involved acted on the consensus. The organizations' altruistic and dedicated advocacy for patent reform and a first-inventor-to-file system began as early as the 1980s, and those involved, specifically including and not limited to Mr. Armitage, representative of NAM, AIPLA, ABA-IPL, and Lilly, and representative of the consensus of the whole patent user community, advocated from the beginning expressly for a patent system for this 21st century, not one of the immediately past century, including the curtailment and elimination of "secret prior art" from being prior art in their proposed first-inventor-to-file system. As in the Statement of Facts, Congress passed the AIA in direct response to these organizations' multi-year and multi-decade efforts on behalf of the country, one that competes in a world of global technological innovation of tens of countries, including, prominently, China, Japan, Korea, other Asian countries, many European countries, and American countries, not one of U.S. innovation competing with British or perhaps British and German innovation alone.

As early as 2007, the 2007 Report 110-259, submitted by Senator Leahy, made an "alpha" statement that anything to be considered prior art "must be publicly available." 2007 Rep. at 9; Manzo at 17.

As early as 2009, in the 2009 Report, also submitted by Senator Leahy, at 6, the alpha statement was repeated.

In 2011, Senator Leahy added an "omega" statement to the alpha 2007 and 2009 Senate Report statements—well before the signing by the President, and thus within the limits of the legislative history, a history that could end only as of Presidential signature—that §102(a)(1) "was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art." 157 Cong. Rec. S1496-S1497. (daily ed., March 9, 2011), (Statement of Sen. Leahy).

As reflected in the Statement of Facts, the legislative record and public history between and after the alpha and omega statements are replete with utterly consistent statements of the many participants in the legislative process that secret sale prior art is eliminated by the AIA. While in 2011 there was surprise contentiousness over the first-inventor-to-file system, never was there anything undercutting or curtailment of the scope of the on sale bar (along with its companion expansion to worldwide coverage) that was present in the Patent Reform Acts of 2007 and 2009 and their Reports.

The USPTO participated in Congressional efforts to fashion and pass the AIA and Patent Reform Acts of 2007 and 2009, at the request of Congress in 2005, and was perfectly aware of matters such as the alpha, omega, and all the

confirmatory explanations of the potential laws' contents as to the necessity of public accessibility of claimed inventions for them to be prior art. So when, just after the passage of AIA, the USPTO informed the numerous organizations that the "AIA does not include the pre-AIA use of secret sales as prior art," the USPTO no doubt knew what it knew, correctly stated what it knew, and the organizations no doubt believed the USPTO, because they knew that truth too.[9]

A principal representative for the organizations in patent reform, and unquestionably the single prime reporter of the patent reform that resulted in the AIA across all the years of efforts to pass it, Robert Armitage of NAM, AIPLA, ABA-IPL, and Lilly, also assured the organizations *and assured Congress itself* further that "secret sales" were "not ... prior art" in authoritative explanations. *E.g.*, R. Armitage, 40 AIPLA Q. J. 1 (2012) ; *Statement of Robert A. Armitage*, May 16, 2012 at 2 ("Congress took bold steps ... The 'loss of right to patent' provisions were all repealed.").

IV. The "Federico of the AIA" thoroughly and consistently affirmed the structure, content, meaning, and legislative history of AIA §102(a)(1).

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[9] *See* https://www.uspto.gov/sites/default/files/aia_implementation/fitf_live_overview_training_slides-march2013.pdf at 13 slide 25.

In interpreting the *pre*-AIA patent law, *i.e.*, the 1952 Patent Act, the courts and patent user community of the late 20th century frequently could consult no better a resource on the meaning of the law than the writings and expressed thoughts of P.J. Federico, the USPTO historian and a principal draftsman of the 1952 Act.[10] For example, this Court quoted Mr. Federico's testimony before Congress in interpreting the law. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 n. 6 (1980).

This Court in this case on the interpretation of the AIA could do no better for the meaning of the AIA than turn to the writings of Mr. Armitage, fairly to be called the "Federico of the AIA." Indeed, if anything, Mr. Armitage is many things more than what Mr. Federico was, in being a readily identifiable single human representative of many AIA-critical organizations and the prime reporter over all the years of the change to a United States patent system for this 21st Century, the AIA.

Mr. Armitage began listening, speaking, and testifying to Congress about a first-inventor-to-file system, that the AIA now effects, decades earlier than the passage of the AIA. He listened to and spoke for NAM, AIPLA, ABA-IPL, Lilly—and indeed Congress itself—in explaining the need, benefits, and particulars of the new law. He was one of only 4 people acknowledged and thanked for being "key members of the 21st Century Coalition for Patent

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[10] *See* https://en.wikipedia.org/wiki/Pasquale_Joseph_Federico.

Reform, who have devoted countless hours" to the AIA, who "stuck with it through thick and thin," "formed a 'kitchen cabinet' ... indispensable to the ... drafting of this bill," and had "a key role in the creation of the America Invents Act." Congressional Record March 8, 2011 S1394. Some in the patent user community consider him at least "one of the principal architects of the AIA," N. Pierce, *Inventorship, Double Patenting, and the America Invents Act*, 30:2 Berk. Tech. J. 1613, 1626 (2015). But most like Federico the historian, he was the prime reporter on the passage of the AIA from early days through and beyond its passage.

Mr. Armitage was awarded entry into the IP Hall of Fame for his stature in patent law and being what he was as to the AIA, "a tireless campaigner for US patent reform."[11] The Chair of the ABA IPL Section who followed Mr. Armitage as Chair awarded him the first page of the bill that became the AIA, framed, in additional recognition of his efforts. As in the Statement of Facts, Mr. Armitage wrote profusely, directly, consistently, and informed by full knowledge of Congressional statutory words and intentions, that the AIA was not to have decisions made about it such as that made by the Federal Circuit panel, in response to the advocacy of academics or otherwise.[12] His views are corroborated

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[11] IP Hall of Fame, Inductees, https://www.iphalloffame.com/home/inductees/ (last visited Aug. 27, 2018).

[12] None of the other three people who were key members and had a key role in the creation of the AIA have written as he has.

by authoritative others. And the academics who will be addressed next were not there; they did not dwell in the decades and with the organizations and the Congresses of the law's creation over the many, many years.[13] Mr. Armitage did.

V. Debate over AIA §102(a)(1) is a regressive, after-the-fact, academic manufacture

What has happened to the AIA to cause the Federal Circuit panel's *Helsinn* decision is not a dispute over the content of AIA §102(a)(1), the stated events of the legislative history, especially not a consensus resulting from a NAS empirical study, or the status or pronouncements of all involved including Mr. Armitage. It is instead a regressive, after-the-fact, small-group-academic manufacture of a dispute over the meaning of AIA §102(a)(1), *compare, e.g.*, Brief of Amici Curiae 42 Intellectual Property Professors, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017) ("Individual Academics Brief") with the AAU letter from thousands of prestigious academic institutions.[14] The ponderings and wanderings of

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[13] Prof. Lemley testified once limited to bad patents, injunctions, damages, and venue. Mr. Armitage rightly humbly credits the NAS 2004 report that provided patent consensus as the motive force behind the AIA.

[14] The academic brief admits the academics "sign in their individual capacity." Individual Academics Brief at *ii*. Some contradict their institutions, who signed on to the AAU letter, *supra* at 16.

this small-group "no-change-to-the-on-sale-bar" side of this manufactured dispute, however, do not change the structure, content, meaning, history, purpose, background, or "revolution" of the AIA, as known to Congress, the USPTO, advocating and attentive organizations, and the mavens of the patent reform, especially those who were in-the-trenches, and most especially the most trustworthy spokesman and historian, Mr. Armitage.

Consistent with everything that everyone but one party, Johnny-come-latelies, and the Federal Circuit panel have written, AIA prior art law has a sole focus on the public availability of a claimed invention itself, not an inventor's on sale actions or terms of sale in relation to some loosely considered invention. AIA §102(a)(1) states the focus is whether "*the claimed invention* was patented, described in a printed publication, *or* in public use, on sale, *or* ***otherwise available to the public*** ..." (emphasis added). The subject of inquiry is always "the claimed invention." It is never the inventors' actions or terms of sale. As Federico of the AIA Mr. Armitage stated to Congress itself, it is at best "difficult to understand how any holistic reading of the new definition of prior art under §102(b) could lead to a conclusion" consistent with that of the few academics. Armitage, 40 AIPLA Q.J. at 8-9. As said by Manzo at 7-10, *see* also 19-20, "availability to the public is the touchstone for determining whether something is prior art, and secret uses or sales are not intended by Congress to form prior art for patents granted under the new FITF [first-inventor-to-file] system."

Nothing in the AIA—which (a) embodied Congress's "bold steps" in overhaul of past patent prior art law to give the U.S. a first-inventor-to-file system, (b) revised 35 U.S.C. §102(a)(1) to have the described specific structure, content, and meaning, and most specifically to have the phrase "available to the public" to "emphasize that" anything to be prior art "must be publicly available," as in the 2007 and 2009 Reports at 6 and 6, respectively, *see* Manzo at 17, and (c) "was drafted ... *to do away with* precedent under current law that private offers for sale ... may be deemed patent-defeating prior art," Cong. Rec. S1496 (emphasis added)—justified the Federal Circuit's improper change of focus from public availability of an invention to public knowledge of an inventor's actions

VI. The essence of the Federal Circuit panel's *Helsinn* decision under review is its conclusion to the opposite of AIA §102(a)(1).

The essence of the Federal Circuit panel's *Helsinn* decision under review is its conclusion that for an invention that is subject to the AIA, if the existence of the terms of a sale were to be publicly known, the sale were to be by an inventor, and the sale were to be of the invention, then the invention is legally publicly known, even if the invention is not factually publicly known:

> [The court] conclude[s] that, after the AIA, if the existence of [a] sale is public, the details of the invention need not be publicly disclosed in the terms of sale

> [for] the ... AIA on-sale bar [of AIA 35 U.S.C. §102(a)(1) to] apply."

Helsinn at 27, Pet. App. A at 43a.

As in the Summary above, stated differently, this is a conclusion that if the terms of sale of an on sale activity of a claimed inventor does not make an invention available to the public, such that the public cannot make or use that invention just by knowing the terms of sale, nevertheless, public knowledge of the terms of sale makes the invention available to the public as a matter of AIA prior art law. This conclusion therefore renders the on sale activity potentially invalidating prior art to a later-filed AIA patent on the invention, if the fact of the existence of the on sale activity by itself were to have been available to the public at the time of the on sale activity.

The Federal Circuit panel's decision is contrary to AIA §102(a)(1).

VII. The Federal Circuit panel's conclusion is a *Pfaff*-like mistake. It is a dramatically odd and wrong interpretation for the AIA based not only on the specific structure, content, and meaning of AIA §102(a)(1), but also the consistent statements from Congress, all those involved in the passage of the AIA, and the "Federico of the AIA," from 2007 to the present, that are contrary to the interpretation.

The Federal Circuit panel's *Helsinn* interpretation is a dramatically odd interpretation of AIA §102(a)(1).

This is no different in kind than the mistake the Federal Circuit made in *Pfaff*. As happened in *Pfaff*, the Federal Circuit has made an on sale decision by wrongly focusing on a matter that is completely absent from the relevant text of §102. In *Pfaff*, *see* at 66-68, the pre-AIA §102 text did not reference "substantial completion," but that was the focus of the Federal Circuit decision, that this Court reversed. Here, the text of AIA §102 does not reference "terms of sale," but terms of sale are the focus of the Federal Circuit's decision. Just as in *Pfaff*, the decision here should be reversed.

The Federal Circuit panel's interpretation of the AIA is completely at odds with its specific structure, content, meaning, history, purpose, background, and revolutionary nature. The Federal Circuit panel was wrong to make the AIA otherwise. It was wrong to snatch from Congress, the USPTO, patent reforming organizations, and their representatives, especially those present in the moment, some of the bold patent reform that the AIA accomplished.

VIII. Small-group academic arguments against the right interpretation of AIA §102(a)(1) are flawed.

The small-group academic arguments against the right interpretation of the AIA in this case are flawed.

Starting an analysis anywhere but the words of §102(a)(1), as the individual academics do, Individual Academics Brief at 2-5, is wrong. As well, generic rules of statutory interpretation must yield to the specific case where structure, content, meaning, import, intention—are openly known. A parade of potential horribles for future burdens on academics and the courts to learn new law does not change AIA §102(a)(1).

The "revolution" that is AIA must be recognized. The academics and Federal Circuit panel also rely on lack of reference to multiple specific past cases about loss of patent rights due to secret on sale activity, but the reliance must be dismissed. Congress was rewriting essentially *all* of patent law. It was rewriting all of prior art law. It was removing all of forfeiture-of-right-to-patent provisions from the law. Congress was handling and frying so many big fish in the passage of the AIA, with thirty-one distinct areas of reform under consideration, that it can hardly be criticized for not speaking about each scale, each precedent, it was de-scaling from the law. That is especially true where it spoke to the de-scaling in sweeping terms, of sweeping away centuries of patent law, and *by speaking about the categories being de-scaled,* such as that §102(a)(1) "was drafted in part to do away with precedent under current law that private offers for sale or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art." 157 Cong. Rec. S1496. Congress left to the prime movers of the organizations who drove the reform effort, the USPTO and historians, including

especially Mr. Armitage, the job of explaining the details of the de-scaling. They did, unwaveringly.

Moreover, Congress can hardly be blamed for not giving a chapter and verse statement of what it found wrong with the past law, because it was *not* gutting the law of the past, that is, the law that was *still to exist and to apply to all ongoing pre-AIA patents and their examination and dispute resolution in litigation and otherwise.* Instead, it was in fact leaving most of the existing law untouched, and in effect, for all those pre-AIA patents that continue to exist in great numbers to this day and will exist in large numbers for about the next 20 years, or more. For AIA patents, Congress was replacing the past law essentially *in toto*, true, but for all pre-AIA patents and for a significant period of the future, it was also leaving the past law intact *in toto* for all pre-AIA patents. That notably explains, for example, why Congress did not reference in its reports the Court's recent on sale bar case, *Pfaff*, which has a two-part test for the on sale bar, neither part of which is secrecy or public availability of the claimed invention. *Pfaff* was to remain—does remain—good law, not being overturned. It is good law, for pre-AIA patents—but it must now fit within AIA §102(a)(1) with its two-part test applied to on sale activities that make a claimed invention publicly accessible, and not to on sale activities that do not make a claimed invention so accessible.

Congress passed the AIA with inventor forfeiture-of-right-to-patent provisions removed from the law for many good and valid reasons, explained eloquently in the briefs of others, such as the Brief

for *Amicus Curiae* Congressman Lamar Smith in Support of Petitioner in this case, March 27, 2018, counsel of record—Robert A. Armitage. These include "transparency, objectivity, predictability, and—above all—simplicity." *Id.* at 1. Eliminating forfeiture-of-right-to-patent provisions is critical to transparency, objectivity, predictability, and simplicity because everyone in the patent system at all stages of activity in relation to patents can, in the new patent system with this elimination, assess patent validity much more predictably, without concern that secret events could upset assessments, such as those events to be revealed usually in the future only after expensive litigation-discovery fights. Retaining forfeiture provisions greatly complicates all of the patent system and patent practice, as it did in the past, and as wanted to be eliminated in the future.

"[N]o reading of the new statute [the AIA] can contort the words ... to fit therein [an] on sale bar [that is a forfeiture-of-right-to-patent provision as in the *Helsinn* panel decision]." *Id.* at 5. That is correct, as a matter of staying true to transparency, objectivity, predictability, and simplicity, as Congress, the USPTO, and all advocating organizations and persons for the AIA wanted and want.

As in Armitage, 40 AIPLA Q. J. at 8, quoted above, "Congress completed a statutory patent revolution":

> [The] terms "in public use or on sale" [were] modified and qualified by a new phrase that reads in its entirety: "in public use, on sale, or

> otherwise available to the public." Congress employed this mechanism to impose an overarching requirement for availability to the public in order for a prior disclosure to constitute prior art. ... The overarching requirement for a disclosure to be "available to the public" has been placed into new §102(a)(1) in a manner making it virtually impossible to read it other than as an express repudiation of the Metallizing Engineering doctrine.

The Court should read the new phrase "in public use, on sale, or otherwise available to the public" as "impos[ing] an overarching requirement for availability to the public," and not do what is "virtually impossible." The phrase was "placed into §102(a)(1) in a manner making it virtually impossible to read it" other than imposing the overarching requirement. The change wrought by AIA §102(a)(1) is not anything like an "elephant" placed in a "mouse hole," either. The change is the open capture and elimination of a pesky mouse, secret prior art, with a big mouse trap, namely the express structure, content, and meaning of AIA §102(a)(1).

IX. The Court should not concern itself that some future inventors might take benefit of both trade secrecy and later patenting; the matter is already handled.

Finally, this Court should not concern itself that a few or more future inventors under the AIA might take the benefits of both trade secrecy and later patenting. The world of competing inventions and inventors in the 21st Century is *sui generis* from the past, and now global. The world of use and sale prior art is also *sui generis* from the past, and again global. As well as patenting and publications, the world of use and sale prior art is now universal among all but few of the world's billions of humans. And the drive to be the first inventor to file anywhere in the world and thereby first under the AIA reaches to all corners, wherever innovation is found, because, to coin a phrase for the world's harmonized patent systems, "to the first filer go the spoils." Worldwide impetus to compete and be first takes more than full care of those who would think to game the system, at a much higher level than a narrow on sale forfeiture aspect such as U.S. patent law had pre-AIA. Indeed, the patent community, Congress, and the AIA, especially the AIA, *have* already taken care of gamers.

CONCLUSION

The Federal Circuit panel should be reversed, to the benefit of a revolutionary patent system for this revolutionary century.

Respectfully submitted,

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No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF NEITHER PARTY

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August 21, 2018

281739

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I

INTEREST OF *AMICUS CURIAE*

Amicus curiae Intellectual Property Owners Association (IPO) is an international trade association representing companies and individuals across all industries and fields of technology who own or are otherwise interested in intellectual property rights.[1] IPO's membership includes about 200 companies and over 12,000 individuals who are involved in the association, either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property before Congress and the United States Patent and Trademark Office (USPTO), and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.[2]

INTRODUCTION

IPO's members invest tens of billions of dollars annually on research and development, employing hundreds of thousands of scientists, engineers, and others in the United States to develop, produce, and market

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1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. Both parties have consented to the filing of this brief.

2. IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

innovative new products and services. Many of these innovations take years of research, failure, missteps, and refinements to reach eureka moments, and still additional time to develop practical applications followed by potential commercialization.

Because of the need to timely file for patents on their innovations, this case presents a question of substantial practical importance to IPO members: namely, whether in enacting the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (AIA) Congress changed the on-sale bar defense to exclude "secret sales" where the invention is not made public. IPO, the trial court, and the USPTO have all concluded that Congress did indeed make such a change to the on-sale bar defense; a determination with which the Federal Circuit disagreed. This Court's resolution of the proper application of the on-sale defense post-AIA is consequential because it will instruct IPO members, as well as the parties, and indeed all intellectual property stakeholders, how to conduct their business and protect their innovations without triggering an on-sale bar.

SUMMARY OF ARGUMENT

At issue on appeal is whether Congress changed the "on-sale" bar to patentability raised as a defense to a patent infringement assertion in enacting the AIA in two aspects: first, whether the post-AIA on-sale bar excludes private sales; and second, whether a public sale requires that the claimed invention subject to the sale be made public to be invalidating.

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) held that Congress did not "change the statutory meaning of 'on sale'" by enacting the AIA, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1360 (Fed. Cir. 2017). The Federal Circuit decision, however, is contrary to the fundamental policy underlying the patent system of encouraging innovation by awarding patents for the public disclosure of the innovation to be protected. Also lost is the practical reality of operations in the present global economy that many complex innovations require arms-length collaboration with third parties to refine and bring those innovations to market. In addition, the Federal Circuit decision disregards the proper tenets of statutory construction and the meaning of "available to the public" as recited by the post-AIA on-sale bar, as well as the apt legislative history.

The Federal Circuit's holding that the mere existence of a public sale or offer for sale that does not disclose the invention as claimed is inconsistent with that part of the Federal Circuit's *en banc* decision in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) stating that "the offer or contract for sale must unambiguously place the invention on sale, as defined by the patent's claims." *Helsinn*, 855 F.3d at 1366. It also finds no support in this Court's precedence and is inconsistent with the USPTO's post-AIA examination guidelines, adopted before the AIA became effective and still followed today. *See* U.S. Patent and Trademark Office, Manual of Patent Examining Procedure § 2152(d) (9th ed., 08.2017 rev., revised Jan. 2018) (MPEP). These examination guidelines were previously the only authoritative guidance post-AIA on whether an invention was on-sale to bar patentability. Indeed, the USPTO's guidelines have governed examination of many hundreds of thousands of patent applications.

More post-AIA innovations are being made, applications are being filed, and patents are being issued every day— the validity and value of many of those patents will remain clouded until this Court settles the present on-sale bar debate. Similarly, both large and small innovators and their business partners need clarity now, so they can organize their businesses and contracts to develop and commercialize innovations while mitigating risks to protection when contracting with others to bring such innovations to market.

IPO believes Congress intended, and that it is the best policy for the U.S. patent system that under the AIA an inventor's sale of an invention to a third party that is obligated to keep the invention confidential does not trigger the on-sale bar and does not qualify as prior art for purposes of determining the patentability of the invention as claimed in a later filed patent application.

ARGUMENT

I. Proper Application of the Post-AIA On-Sale Bar Is Critically Important to All Industries and Fields of Technology

This case presents an important issue of first impression: whether Congress substantively changed the on-sale bar in section 102 of the Patent Act when it enacted the AIA. Congress made fundamental changes to the Patent Act by, among other things, redefining prior art under section 102. *See Helsinn*, 855 F.3d at 1368. The Federal Circuit expressly declined, however, to address how those changes, which it deemed limited to "public use" activities, affect application of the on-sale bar, *see*

id. at 1368-69, a critically important issue that this Court should decide.

Interpretation of the post-AIA on-sale bar as requiring public disclosure of the invention is consistent with a policy of encouraging innovation and recognizing that many complex technological developments require collaboration with third parties to refine and commercialize inventions. Indeed, to bring new products and services to market, smaller inventors often resort to contractual arrangements with third parties for supply and/or distribution because size and capital constraints prevent the internal execution of such functions. Other inventors that have deep internal resources might or might not contract with third parties to bring their innovations to market. Regardless, complexity in factors such as manufacturing, supply chain, and distribution in many industries dictates that plans for commercialization begin years before research and development has produced marketable products, particularly, for example, in the pharmaceutical, semiconductor, energy, aerospace, and automotive industries.

By way of specific example, there exists a close working relationship in the semiconductor industry between chip manufacturers and semiconductor processing equipment suppliers. In this innovation ecosystem, chip manufacturers often focus on product design, relying on equipment suppliers to design and build manufacturing equipment to fabricate such designs. Although chip manufacturers focus on chip design, they also develop new processing inventions to help achieve particular design features. In those cases, the chip manufacturer works with an equipment supplier to develop equipment that can execute such processing inventions. In such

circumstances, purchase agreements for equipment that implements those new processing inventions could give rise to an on-sale bar under the Federal Circuit's current interpretation of the law.

Other examples are found in the aerospace and automobile industries. There, similar relationships exist between the innovator and the suppliers who must plan often years in advance of commercialization of an invention, to develop the tools and processes to supply components and substructures first as prototypes to establish proof of concept, and if successful later as commercially viable components for commercial release. In these circumstances too, arm's length agreements regarding the development and supply of components could give rise to an on-sale bar under the Federal Circuit's current interpretation of the law.

It goes without saying that the biopharmaceutical industry, as presented by the facts of this case, presents another important example.

Allowing innovators to enter into sales contracts with third parties provides a means for developing innovations that might not come to fruition without third party collaboration, an outcome that appears to frustrate the purpose of the patent laws. Such freedom allows inventors to contribute innovations where they would not otherwise have the capital infrastructure or other necessary resources to fully refine an invention, while also fostering the development of inventions that require experience across several industry or technical domains. Although third party sales and collaboration have historically been prevalent in certain industries, such activities are becoming ever more important

across an increasing number of industries, for example, technological integration of hardware and software in industries proliferating around the Internet of Things (IoT) and Artificial Intelligence (AI).

II. The Post-AIA On-Sale Bar Provision Should Be Interpreted to Exclude Secret Sales

a. Statutory Construction Principles Confirm That Congress Intended to Exclude Secret Sales from the On-Sale Bar

When Congress amended the on-sale bar provision of section 102, it added the phrase "or otherwise available to the public." A comparison of the old and current on-sale bar provisions are presented below.

Pre-AIA 35 On-Sale Bar, 35 U.S.C. § 102(b)	35 U.S.C. § 102(a)(1)
A person shall be entitled to a patent unless – ... (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States	(a) Novelty; Prior Art. – A person shall be entitled to a patent unless-- (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention

Although the Federal Circuit considered Petitioner's statutory construction argument, it found that the "series-modified" doctrine was not applicable (Concurrence *En Banc* Decision at 6-9) and thus determined that the statute did not exclude secret sales. The Federal Circuit's interpretation of the statute, however, does not give effect to the "otherwise available to the public" language added by Congress. This Court has held that a reading of a statute that gives an amendment no effect cannot be correct. *See Pierce City v. Guillen*, 537 U.S. 129, 145 (1995) ("[W]hen Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect.").

Conversely, a plain reading of the statute and canons of statutory construction confirm that secret sales are excluded from the on-sale bar because "or otherwise available to the public" modifies "on sale." Beyond such an interpretation giving effect to all language comprising the amended statute, courts have consistently construed the words "or otherwise" or "or other" at the end of a string as modifying the preceding clauses. *See, e.g., Strom v. Goldman, Sachs & Co.*, 202 F.3d 138, 146-47 (2d Cir. 1999), *abrogated on other grounds; Universal City Studios, Inc. v. Reimerdes*, 111 F. Supp. 2d 294, 325 (S.D.N.Y. 2000).

Dictionary definitions and the plain meaning of the word "otherwise" refer to a "different" or "other way." In this case, a different or other way that the invention can be made available to the public. *See, e.g.*, Brief of *Amicus Curiae* US Inventor, Inc. in Support of Petitioner Helsinn Healthcare S.A.'s Petition for a Writ of Certiorari at 10-11. Further in this regard, under the principle of *noscitur a sociis*, *i.e.*, a word is known by the company it keeps, the

phrase "on sale" should be interpreted by association with the phrases around it, namely, "in public use" and "otherwise available to the public." *See Yates v. U.S.*, 135 S. Ct. 1074, 1085 (2015) ("[W]e rely on the principle of *noscitur a sociis*—a word is known by the company it keeps— to avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress.") (citation and internal quotation marks omitted).

The Federal Circuit has thus improperly broadened the on-sale bar post-AIA by disregarding language Congress added to the statute that requires the invention on-sale be made available to the "public" to qualify as prior art.

b. The Legislative History of the AIA Confirms That Secret Sales Were Meant to Be Excluded

The AIA legislative history is replete with commentary from Congress regarding the amendments to section 102(a). These statements confirm that it was Congress' intent to limit non-patent prior art to that which is available to the public.

In 2008, Senator Kyl explained that the patent system will be "simpler and more transparent ... [b]y eliminating confidential sales and other secret activities as grounds for invalidity and imposing a general standard of public availability." 154 Cong. Rec. S9992 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl). This change to section 102(a) would "provide greater certainty and predictability," as well as "substantially reduce the need for discovery in patent litigation, since defendants will no longer need to

uncover evidence of private sales or offers for sale or other nonpublic information in order to determine whether the patent is valid." *Id.*; *see also* 157 Cong. Rec. S5319 – S5320 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl) ("The main benefit of the AIA public availability standard of prior art is that it is relatively inexpensive to establish the existence of events that make an invention available to the public.").

In the March 2011 Senate debate on the AIA, Senator Kyl explained that the word "otherwise" was added to section 102(a) to eliminate secret sales:

> Another aspect of the bill's changes to current section 102 also merits special mention. New section 102(a)(1) makes two important changes to the definition of non-patent prior art. First, it lifts current law's geographic limits on what uses, knowledge, or sales constitute prior art. And second, ***it limits all non-patent prior art to that which is available to the public.*** This latter change is clearly identified in Senate Report 110–259, the report for S. 1145, the predecessor to this bill in the 110th Congress. ***The words "otherwise available to the public" were added to section 102(a)(1) during that Congress's Judiciary Committee markup of the bill. The word "otherwise" makes clear that the preceding clauses describe things that are of the same quality or nature as the final clause— that is, although different categories of prior art are listed, all of them are limited to that which makes the invention "available to the public."*** As the committee report notes at page 9, ***"the phrase 'available***

> ***to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it [i.e., the relevant prior art] must be publicly available.*** In other words, as the report notes, "[p]rior art will be measured from the filing date of the application and will include all art that publicly exists prior to the filing date, other than disclosures by the inventor within one year of filing.

157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (emphasis added).

Congress was well aware of the principles of statutory construction during the drafting of amendments to section 102(a), and intended for the phrase "or otherwise available to the public" to modify and restrict the preceding phrases "in public use" and "on sale":

> The Committee's understanding of the effect of adding the words "or otherwise available to the public" is confirmed by judicial construction of this phraseology. ***Courts have consistently found that when the words "or otherwise" or "or other" are used to add a modifier at the end of a string of clauses, the modifier thus added restricts the meaning of the preceding clauses.*** ... In other words, the Judiciary Committee's design in adding the 2007 amendment to section 102(a)(1), as expressed in the relevant committee report, is consistent with the unanimous judicial construction of the same turn of phrase. It appears that every court that has considered this question agrees with

> the committee's understanding of the meaning of this language. Moreover, ***the fact that the clause "or otherwise available to the public is set off from its preceding clauses by a common confirms that it applies to both "public use" and "on sale"*** .... Thus new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated by the bill—an understanding on which the remainder of the bill is predicated.

157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (emphasis added); ***see also*** 157 Cong. Red. S5431 (daily ed. Sept. 8, 2011 (statement of Sen. Kyl) ("When the committee included the words 'or otherwise available to the public' in section 102(a), ***the word 'otherwise' made clear that the preceding items are things that are of the same quality or nature. As a result, the preceding events and things are limited to those that make the invention 'available to the public.'***") (emphasis added).

Apart from Senator Kyl, Senator Leahy, one of the lead sponsors of the AIA, confirmed that "subsection 102(a) was drafted in part ***to do away with*** precedent under current law that ***private offers for sale*** or private uses or secret processes practiced in the United States that result in a product or service that is then made public may be deemed patent-defeating prior art." 157 Cong. R. S1496 (daily ed. Mar. 9, 2011) (statement of Sen. Leahy) (emphasis added).

Policy reasons guided Congress' changes to section 102(a) because "the [prior] on-sale bar impose[d] penalties not demanded by any legitimate public interest. There is

no reason to fear 'commercialization' that merely consists of a secret sale or offer for sale but that does not operate to disclose the invention to the public." 157 Cong. Rec. S1371 ("The current forfeiture doctrines have become traps for unwary inventors and impose extreme results to no real purpose."). The changes to the on-sale bar provision were highlighted by Senator Kyl because "the bill's imposition of a general public availability standard and its elimination of secret prior art ... are no small matter." *Id.*

Thus, Congress believed that allowing "private and non-disclosing uses and sales to constitute invalidating prior art" under section 102(a) "would be fairly disastrous for the U.S. patent system" and the validity of patents would "depend on discovery-intensive searches for secret offers for sale and non-disclosing uses by third parties." *Id.* Moreover, eliminating secret sales from the on-sale bar was considered "a necessary accompaniment to [the] elimination of geographic restrictions on the definition of prior art" because invalidating secret offers for sale in foreign countries might "place U.S. inventors at grave risk of having their inventions stolen through fraud." *Id.* This was a risk that Congress was not willing to accept. *Id.*; *see also* 157 Cong. Rec. S5320 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl).

The Federal Circuit's dismissal of the legislative history because it was tied to overruling case law related to public use, but not the on-sale bar, does not withstand scrutiny. First, the legislative history does support a construction that excludes secret sales from the on-sale bar, and second, the same policy that excludes secret uses also supports excluding secret sales, as this Court has long recognized. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55,

68 (1998) (citing to a private use case to support when an invention is ready for patenting in determining whether the on-sale bar is met).

III. Excluding Secret Sales Is Consistent with Congress' Intent for the AIA to Harmonize United States Patent Laws with Other Countries

Section 3(o) of the AIA notes Congress' intent to harmonize United States Patent laws with those of other countries:

> SENSE OF CONGRESS.--It is the sense of the Congress that converting the United States patent system from "first to invent" to a system of "first inventor to file" will promote the progress of science and the useful arts by securing for limited times to inventors the exclusive rights to their discoveries and provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries.

This statement recognizes that the pre-AIA statutory structure embraced a first-to-invent system, whereby an inventor did not have to be the first to file a patent application on an invention and could show that he or she had possession of the invention prior to another to be entitled to a patent. Given the first-to-invent approach, there was a desire to make sure inventors timely filed their patent applications and did not commercialize their invention and then later file an application. Thus, the pre-AIA on-sale bar served the purpose of encouraging timely application filings.

The post-AIA statutory structure is different. It adopted the approach used by almost all other countries, whereby the application filing date dictates what is and what is not prior art with respect to that application. In those other countries, secret sales, *i.e.*, sales that did not publicly disclose the invention, were not and are not considered prior art. Accordingly, construing the on-sale bar provision to include secret sales would frustrate the Sense of Congress.

IV. The Federal Circuit Decision Is Inconsistent with Other Interpretations of the On-Sale Bar

Putting aside that Congress redefined "on-sale" post-AIA to exclude sales where the invention is not made known to the public, the result below is inconsistent with *Medicines*, this Court's precedence, and the USPTO's examination guidelines implementing the AIA. It should not stand.

a. The Federal Circuit's *En Banc* Decision in *Medicines* Compels a Result That the Invention Was Not On-Sale in the Present Case

Medicines allows inventors to contract for manufacturing services without triggering the pre-AIA on-sale bar, provided their inventions (as defined by a patent's claims) are not "on sale." 827 F.3d at 1374 (application of the on-sale bar "requires that 'the invention' be 'on sale'" and "[t]he 'invention' is defined by the patent's claims.") (quoting 35 U.S.C. § 102(b)). *Medicines* further states that, "there must be a commercial sale or offer for sale. The statute itself says the invention must be 'on sale,' or that there must be an offer for sale of the invention....

The on-sale bar is triggered by actual commercial marketing of the invention, not preparation for potential or eventual marketing. . . . It is well settled that mere preparations for commercial sale are not themselves 'commercial sales' or 'commercial offers for sale' under the on-sale bar." *Id.* at 1377.

The Federal Circuit, however, has held that the post-AIA on-sale bar applies to all public sales, including sales that do not disclose an invention as defined by the patent claims, holding that "an invention is made available to the public when there is a commercial offer or contract to sell a product embodying the invention and that sale is made public" and that ("after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." *Helsinn*, 855 F.3d at 1370-71.

This result is inconsistent with *Medicines* in at least two respects. First, the Federal Circuit decision does not allow inventors the same flexibility for contracting with third parties for license and distribution agreements that must be publicly disclosed that *Medicines* allows for manufacturing agreements that need not be disclosed. Yet neither makes the invention known to the public and there is no principled basis to support inconsistent results.

Second, *Medicines* makes it crystal clear that the alleged sale must unambiguously place the invention on sale and be actual commercial marketing. An inventor's contract, whether for manufacturing or licensing, public or private, amounting to mere preparation for the potential or eventual commercialization does not amount to an invalidating offer for sale, or sale. To hold otherwise would

illogically penalize small innovators who must rely on third parties to prepare for commercialization. Moreover, such a result would serve to doubly penalize small innovators who collaborate with companies having public reporting obligations. It results in further unfair treatment relative to vertically integrated innovators who perform the exact same conduct—except that all such activities are under one corporate roof—to prepare for commercialization in the same way. In both circumstances, however, the claimed invention is not yet disclosed to, or used by the public.

b. The Federal Circuit's Decision Does Not Square with *Pfaff*'s Requirement That the Invention Be Public to Be On Sale

This Court's most recent consideration of the on-sale bar reviewed the origins and policy underpinnings of the doctrine, as well as confirmed that the on-sale bar applies "when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale.... Second, the invention must be ready for patenting." *Pfaff*, 525 U.S. at 67. In reaching this two-part test, the Court consistently noted that the invention claimed had to be given up to the public to be on-sale. *See id.* at 64 ("§ 102 of the Patent Act serves as a limiting provision, both excluding ideas that are in the public domain from patent protection and confining the duration of the monopoly to the statutory term.... A similar reluctance to allow an inventor to remove existing knowledge from public use undergirds the on-sale bar."); *see id. at* 65 ("The patent laws therefore seek both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention."). But the

Court has not before held that the on-sale bar applies to non-public sales, particularly conditional sales made prior to any actual commercialization where, although the fact of the conditional sale was known, the invention claimed was neither known to nor used by the public.

The Federal Circuit's extension of the on-sale bar to non-public sales has no support in this Court's precedence, does not cite any compelling rationale for such an extension, and should be rejected. In this regard, the Concurring Opinion reveals an inexplicable inconsistency in the Federal Circuit's holding. On the one hand, the Federal Circuit rejected the legislative history argument that the post-AIA on-sale bar excludes secret sales because the cases discussed by Congress were *public use* cases, but "not any *sale* cases that would be overturned by the amendments." *Helsinn* 855 F.3d at 1369. On the other, the Concurring Opinion embraced this Court's endorsement of the general principles set forth in a *public use* case, *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), regarding when an invention is ready for patenting. *Helsinn Healthcare S.A. v. Teva Pharms. USA Inc.*, No. 16-1284 (Fed. Cir. Jan. 16, 2018), slip op. at 3-4 n.1 (O'Malley, Circuit J., concurring in the denial of panel rehearing) ("[T]he Supreme Court seems to have endorsed the general principles articulated in *Metallizing*."). Rolling back the Federal Circuit's expansion of the on-sale bar to exclude non-public sales would resolve the inconsistency and comport with both Congress's intent and *Pfaff*, which consistently refers to the need for the invention to be "public" to be on sale.

c. The USPTO's Post-AIA View of the Scope of the On-Sale Bar Excludes Secret Sales

Before the effective date of the AIA, the USPTO adopted its interpretive guidelines, including the only authoritative interpretation of new AIA section 102 until the Federal Circuit decision. *See* MPEP § 2152.02(d). For the last five years, patent applicants and examiners have followed those guidelines in considering what information to disclose and the significance of such disclosures. More importantly, the USPTO has examined hundreds of thousands of patents based on a reading of the on-sale bar that is consistent with the district court's construction below, but inconsistent with the Federal Circuit's construction. According to statistics from the USPTO, just under a million patents were granted between 2013 (the year the AIA went into effect) and 2015. *See* USPTO Patent Technology Monitoring Team, U.S. Patent Statistics Chart, Calendar Years 1963-2015, available at https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last visited March 17, 2018). These numbers are only increasing as time passes.

As discussed above, the Federal Circuit held that, notwithstanding enactment of the AIA, the on-sale bar applies to a public sale even if an invention is not disclosed in the terms of the sale. *Helsinn*, 855 F.3d at 1371. The USPTO's MPEP, however, takes a different view of the scope of the post-AIA on-sale bar. There, "[t]he phrase 'on sale' in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA 35 U.S.C. 102(b), ***except that the sale must make the invention available to the public.***" MPEP § 2152.02(d) (emphasis added). The USPTO's MPEP further states that "[t]he pre-AIA

35 U.S.C. 102(b) 'on sale' provision has been interpreted as including commercial activity even if the activity is secret.... AIA 35 U.S.C. 102(a)(1) uses the same 'on sale' term as pre-AIA 35 U.S.C. 102(b). ***The 'or otherwise available to the public' residual clause of AIA 35 U.S.C. 102(a)(1), however, indicates that AIA 35 U.S.C. 102(a)(1) does not cover secret sales or offers for sale.*** For example, an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if it is among individuals having an obligation of confidentiality to the inventor." *Id.* (emphasis added).

As the USPTO discusses in formulating its examination guidelines, "[r]esidual clauses such as 'or otherwise' or 'or other' are generally viewed as modifying the preceding phrase or phrases," and that "[t]herefore, the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art." U.S. Patent and Trademark Office, Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11059-01, 11062 (Feb. 14, 2013)(citations omitted). Further, the USPTO commented "that the Office's interpretation is consistent with the interpretation that was clearly expressed by the bicameral sponsors of the AIA during the congressional deliberations on the measure." *Id.* (citations omitted).

In addition, the USPTO remarked that "interpreting the 'on sale' provision to require public availability is good public policy in that it would lower litigation costs by simplifying discovery and would reduce unexpected prior art pitfalls for inventors who are not well versed in the law." *Id.*

Under the USPTO's post-AIA construction of the on-sale bar, agreements that do not disclose the claimed invention do not bar patentability or invalidate patent claims because the invention claimed has not "made available to the public." The district court found that to be the situation in this case. *See Helsinn Healthcare S.A. v. Dr. Reddy's Labs. Ltd.*, No. CV 11-3962 (MLC), 2016 WL 832089, at *51 (D.N.J. Mar. 3, 2016). This is consistent with *Pfaff's* requirement that the invention be publicly known to be on-sale. Independent of whether any deference is due to the USPTO, the consistency of its construction with the district court's and this Court's precedence and the disagreement between that construction and the Federal Circuit's construction highlights that the Federal Circuit's construction is the outlier that should be reversed.

d. The Concurrence Misapprehends IPO's *Medicines* Argument

Judge O'Malley took issue with IPO's *Medicines* argument in the concurrence to the denial of the petition for *en banc* for this matter, which she described as a mischaracterization of *Medicines*. *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, No. 2016-1284, 2016-1787, slip op. at 2 (Fed. Cir. Jan. 16, 2018) (O'Malley, J., concurring). Judge O'Malley correctly pointed out that *Medicines*' determination that the agreements at issue did not place the invention on sale was based on a number of factors, including confidentiality, not one of which was "of talismanic significance." *Id.* (citing *Medicines*, 827 F.2d at 1326). IPO agrees, but nevertheless maintains that the weighing of the factors underlying (i) whether the invention was the subject of a commercial sale and (ii) whether the claimed subject matter is made public,

was treated differently and inconsistently in the Federal Circuit decision below, in ***Medicines***, in this Court's precedence, and in the USPTO guidelines, all of which warrants correction by this Court.

Further, the policy discussion in the concurrence below misapprehends IPO's *amicus* position, which is that the Court should determine that Congress changed the on-sale bar, not whether the consequences of applying pre-AIA on-sale bar jurisprudence should be avoided on policy grounds. *Helsinn*, No. 2016-1284, 2016-1787, slip op. at 4-5 (O'Malley, J., concurring). Here, the policy issues bear directly on whether Congress intended to change the on-sale bar to promote innovation, and should be considered in resolving this important question.

In this regard, this Court has previously stated the policy underlying the on- sale bar: "[t]he patent laws therefore seek both to protect the public's right to retain knowledge already in the public domain and the inventor's right to control whether and when he may patent his invention." *Pfaff*, 525 U.S. at 65. After considering that Congress allowed the inventor first a two-year grace period, and then one year, the Court promulgated its two-factor test for the on-sale bar. *Id.* at 65, 67-68. IPO submits this policy focus on "knowledge in the public domain" warrants this Court's confirmation that post AIA the on-sale bar does not embrace secret sales.

CONCLUSION

IPO believes that in enacting the AIA, Congress intended to implement a change in the on-sale bar to exclude secret sales, sales where the invention claimed is not made known to the public, as prior art. The statutory construction, legislative history, and policy of encouraging innovation all support such a result. Moreover, the Federal Circuit failed to consider its *en banc* holding in *Medicines*, the import of this Court's precedence, and the guidance offered by the USPTO that sales must put the invention in the hands of the public before the on-sale bar is triggered.

For these reasons, IPO respectfully requests that this Court confirm that post-AIA § 102(a) requires that a sale must publicly disclose the details of the invention subject to the sale in order to be invalidating.

Respectfully submitted,

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APPENDIX[1]
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1. IPO procedures require approval of positions in briefs by a two-thirds majority of directors present and voting.

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No. 17-1229

In the
Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., et al.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR *AMICUS CURIAE* CONGRESSWOMAN ZOE LOFGREN IN SUPPORT OF RESPONDENTS

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STATEMENT OF INTEREST[1]

Congresswoman Zoe Lofgren represents the 19th Congressional District of California, based in San Jose, California—the heart of Silicon Valley. Rep. Lofgren has a special interest and expertise in intellectual property law, which has often been a focus of her work in Congress. Specific to the question this case presents, Rep. Lofgren was actively involved in the drafting and passage of the 2011 America Invents Act ("AIA") through her work on the House Committee on the Judiciary ("Committee"). She proposed the amendment containing the language retaining the "on-sale bar" at issue in this case, which the Committee adopted and which ultimately became law with the enactment of the AIA. Because of her work championing this amendment against its opponents in Congress, Rep. Lofgren is uniquely well-suited to speak about the AIA's retention of the on-sale bar, including the Committee's work drafting the amendment and the significance of contemporaneous statements from other members of Congress about the specific language adopted in the Act.

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[1] Pursuant to Supreme Court Rule 37.6, *amicus curiae* states that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amicus curiae*, its members, and its counsel, made any monetary contribution toward the preparation or submission of this brief. Pursuant to Supreme Court Rule 37.3, counsel of record for all parties consented to the filing of this brief.

SUMMARY OF THE ARGUMENT

When Congress retained the phrase "on sale" without alteration in the Leahy-Smith America Invents Act of 2011 ("AIA"), Congress clearly intended to preserve the meaning of the on-sale bar as it had long been judicially interpreted, including in many of this Court's own cases. All of the ordinary tools of statutory interpretation point to that result, including the plain language of the on-sale bar and established canons of statutory construction.

The legislative history surrounding the AIA does not undermine this result—it supports it. Congress considered several alternative bills to the AIA that would have achieved the result for which Petitioner now advocates: replacing the on-sale bar with a pure publicity standard. Yet Congress did not adopt the language of those proposals and chose instead to preserve the on-sale bar as it had previously existed. Both advocates and opponents of the on-sale bar contemporaneously acknowledged that retaining the bar also meant retaining its judicially-defined meaning. It was only *after* opponents of the on-sale bar lost their bid to change the AIA's text that individual members of Congress delivered floor statements (notoriously the least reliable form of legislative history) pressing a creative interpretation of the AIA's ultimately-enacted language that would accomplish the very thing Congress had *declined* to do.

Petitioner's legislative history arguments rely on these isolated floor statements, ignoring the overall weight of legislative history and the traditional canons of statutory construction, all of which strongly favor Respondent's position in this case.

ARGUMENT

I. Under The Plain Text Of The America Invents Act, An Invention Is "On Sale" When It Is Offered For Sale.

The words "on sale" in the AIA should be afforded their plain meaning: an invention is "on sale" when it is offered for sale. As Respondents have demonstrated (and as will only be briefly summarized here), whether an item is "on sale" depends on whether it is available for purchase, not on whether any purchase is publicly disclosed. Not only does that reading comport with a commonsense understanding of what "on sale" means, but it is also consistent with what courts rightly assume when Congress retains words previously present in a statute—that when Congress reuses the same language, it intends the same meaning. *See Air Wis. Airlines Corp. v. Hoeper*, 571 U.S. 237, 248 (2014). Here, when Congress enacted the AIA, the term "on sale" had a judicially-established meaning. By continuing to use "on sale" in the AIA, Congress clearly intended to preserve that judicially-established meaning. Congress's addition of the words "or otherwise available to the public" does not change matters. That language *broadens* the range of conduct that invalidates a patent, so it makes no sense to use that language to *constrict* the application of the on-sale bar, as Petitioner would have this Court do. The Court should honor the meaning of the AIA's plain text by maintaining the definition of "on sale" that Congress chose to preserve.

A. As Case Law Made Clear at the Time of the AIA, Whether an Item Is "On Sale" Depends on Its Availability for Purchase, Not Public Disclosure.

The phrase "on sale," by its plain terms, speaks only to the availability of something for purchase, not the public or private nature of any exchange. As Respondent has demonstrated, Resp. Br. 23-24, and as dictionary definitions confirm, a "sale" simply refers to a "transfer of property for money or credit," *Random House Webster's Unabridged Dictionary* 1693 (2d ed. 2001). The focus is on *ownership*, not *disclosure*. Something is "on sale" merely because it is made available for purchase, regardless of whether that availability is extended to all members of the public or only a private group.

When Congress passed the AIA, this Court had long interpreted the phrase "on sale" consistently with its plain language, to cover *any* offer of sale, regardless of whether the offer would disclose the invention to the public. In *Hall v. Macneale*, 107 U.S. 90, 97 (1883), the sale of two safes containing unpatented bolts was enough to trigger the on-sale bar, even though there were only two safes sold and the bolts could be accessed only by destroying the safes. In *Consolidated Fruit-Jar Co. v. Wright*, 94 U.S. 92, 94 (1876), the Court held that "a single instance of sale or of use by the patentee may ... be fatal to the patent," again not requiring that the sale have the effect of disclosing the invention broadly to the public. In *Smith & Griggs Manufacturing Co. v. Sprague*, 123 U.S. 249, 257 (1887), the Court said that "[a] single sale to another ... would certainly ... defeat[ ] [an inventor's]

right to a patent," again without considering whether such a "single sale" would disclose the invention to the public at large.

Though old, these cases are hardly relics, as their holdings have continued to be applied in more recent decisions. In *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67 (1998), for example, an inventor's mere *offer* of an unpatented invention to a single purchaser was enough to trigger the on-sale bar, even though an offer of sale would not, in and of itself, disclose the details of the invention to be sold.

B. Courts Rightly Assume That Congress Intends to Preserve the Meaning of Judicially-Interpreted Terms When It Retains Them in a Statute.

Congress was aware of this Court's longstanding interpretation of the on-sale bar when it chose to retain it in the AIA. Under well-established case law, courts, thus, rightly assume Congress intended to preserve that meaning.

Before the AIA's enactment, 35 U.S.C. § 102 (2006) provided that "[a] person shall be entitled to a patent unless ... the invention was ... on sale in this country[ ] more than one year prior to the date of the application for patent in the United States." Although Congress changed *other* language in this statutory section when it passed the AIA, Congress chose not to disturb the statute's pre-existing use of the phrase "on sale." Thus, after the AIA, 35 U.S.C. § 102 provides that "[a] person shall be entitled to a patent unless ... the claimed invention was ... on sale ... before the effective filing date of the claimed

invention." AIA, Pub. L. No. 112-29, § 3(b)(1), 125 Stat. 284, 285-286 (2011).

When Congress chooses to retain a term of art in a statute, as it did in retaining "on sale" in § 102, courts rightly assume that the choice is purposeful and embraces the existing meaning of the retained term. "It is a cardinal rule of statutory construction that, when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it is taken." *Air Wis.*, 571 U.S. at 248.

This principle holds true especially where this Court has already interpreted the term in question. "[T]he modification by implication of the settled construction" of a statute "is not favored." *United States v. Madigan*, 300 U.S. 500, 506 (1937). Rather, when Congress intends to change the meaning of a term that this Court has interpreted, "it ordinarily provides a relatively clear indication of its intent in the text of the amended provision." *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1520 (2017). *See also* Antonin Scalia & Bryan Garner, *Reading Law: The Interpretation of Legal Texts* 331 (2012) ("Legislative revision of law clearly established by judicial opinion ought to be by express language or unavoidably implied contradiction. We know of no case to the contrary.")

In enacting the AIA. Congress made no clear effort to change the meaning of "on sale." Quite the opposite: Congress did not change the phrase "on sale" *at all*. Congress simply preserved that judicially-interpreted term of art in 35 U.S.C. § 102 without

changing the text or specifying an alternative meaning or new limitation.

Accordingly, a well-established canon of statutory construction counsels this Court to retain its longstanding interpretation of "on sale" in 35 U.S.C. § 102 just as Congress chose to retain those words despite changing other parts of the same statute. Applying this canon serves the additional purpose of allowing Congress to predict the way that courts will interpret the statutory language it enacts. Congress is entitled to legislate against the backdrop of well-recognized judicial canons, as it has done here. *See EEOC v. Arabian Am. Oil Co.*, 499 U.S. 244, 248 (1991) (Court assumed that "Congress legislates against the backdrop of" the well-recognized presumption against the extraterritorial application of statutes). Consistent application of these background interpretive principles lends predictability to statutory drafting and clarity to subsequent judicial interpretation.

C. Congress Added the Phrase "Or Otherwise Available to the Public" to Broaden the Range of Conduct That Could Invalidate a Patent, Not to Restrict It.

To counter the foregoing analysis, Petitioner hangs its hat not on changes Congress made to the "on sale" language (there were none) but on other changes Congress made to the statutory text nearby. Specifically, Congress added the phrase "or otherwise available to the public" to the list of patent-invalidating actions in 35 U.S.C. § 102—the same list that contains the on-sale bar. Thus, the post-AIA

version of § 102 reads: "A person shall be entitled to a patent unless ... the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." Petitioner reads the "or otherwise" addition to this language as modifying the meaning of the list of established terms of art that precede it. Not so.

First, reading "or otherwise available to the public" to modify the list of established terms preceding it would be inconsistent with the canon of statutory interpretation that applies when determining whether Congress has changed the meaning of a term this Court has previously defined. *Supra*, at 5-7. As explained, this Court expects that Congress will "provide[ ] a relatively clear indication of its intent" to change a statute's meaning and disfavors "modification by implication." *TC Heartland*, 137 S. Ct. at 1520 (quoting in part *Madigan*, 300 U.S. at 506). Yet "modification by implication" is precisely what Petitioner thinks Congress did. Petitioner would have this Court *imply* from the addition of the "or otherwise" language that Congress intended to modify the meaning of *every* judicially-interpreted term of art preceding it, essentially a clandestine way of making sweeping changes to existing caselaw. That is flatly inconsistent with how this Court expects Congress to act when it legislates around its precedential decisions.

Second, Petitioner's reading of "or otherwise available to the public" would *contract* the scope of the on-sale bar when that language naturally operates to

expand the categories of patent-invalidating acts. The AIA's addition of "or otherwise available to the public," most naturally (and indeed, obviously) acts as a new, catch-all category encompassing *any* act that makes an unpatented invention available to the public, whether or not that act would otherwise be captured by one of the preceding categories. *See* Resp. Br. at 19, 31-33. The word "otherwise" specifically acknowledges that the preceding categories *sometimes* overlap with the new, catchall category, but it nonetheless allows the catchall category to serve as a statutory gap-filler, ensuring that no act of public sharing escapes inclusion in the list of patent-invalidating acts. Petitioner's interpretation, however, would read the "otherwise" category to *restrict* the applicability of the on-sale bar even as it simultaneously expands the list of patent-invalidating acts as a gap-filler. In other words, Petitioner would read "or otherwise available to the public" to contract the scope of the on-sale bar to only public sales while expanding the list of patent-invalidating acts to include any and all acts that make an unpatented invention publicly available. That reading is unnatural, exceptionally complicated, and frankly, makes little sense.

Third, Petitioner's reading would radically alter the purpose of the on-sale bar (and here again, without any acknowledgment from Congress that it was enacting such a change). The on-sale bar exists to encourage the public disclosure of inventions by discouraging inventors from profiting from their inventions for long periods of time before seeking the benefit of the monopoly granted by patent ownership. This Court's decisions have embraced this policy

rationale. When interpreting the on-sale bar, *see supra* 4-5, the Court has consistently looked not to whether a sale *actually disclosed* an invention to the public (as Petitioner urges the Court to do now) but to whether an inventor *derived a benefit* from the sale of the unpatented invention. *See, e.g.*, *Consol. Fruit-Jar*, 94 U.S. at 94. The policy objective behind the on-sale bar drives this distinction. The on-sale bar allows an inventor the advantage of a patent's temporary monopoly *only* upon prompt disclosure of the patented invention. Enforcing the on-sale bar avoids the problem of "an inventor acquir[ing] undue advantage over the public by delaying to take out a patent" while nonetheless attempting to profit from the invention, thereby "preserv[ing] the monopoly to himself for a longer period than is allowed by the policy of the law." *Pfaff*, 525 U.S. at 64-65 (quoting *City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 137 (1877)). For that reason, the on-sale bar has not historically been concerned with the public's access to the details of an invention but rather with an inventor benefitting from an undisclosed invention *and later* receiving the benefit of a patent's monopoly, too. Petitioner would upend this established policy justification for the on-sale bar and replace it with a publicity rationale, all without any clear language from Congress indicating such a momentous change.

II. The Legislative History Surrounding The America Invents Act Does Not Justify Reading "On Sale" Inconsistently With Its Plain Meaning.

The AIA's legislative history provides no justification for departing from the plain language of

the on-sale bar and the ordinary canons of statutory construction outlined above. No one understands the legislative history behind reenacting the on-sale bar better than Rep. Lofgren, who championed retaining the "on sale" language that ultimately remained in the AIA against vocal opposition in Congress. The legislative history reveals that Congress considered making changes to the on-sale bar when it enacted the AIA but *rejected* those proposals. Contrary statements in the Congressional Record reflect the views of individuals, not the intent of Congress.

A. Congress Explicitly Rejected Versions of the AIA That Would Have Removed or Modified the On-Sale Bar.

During the years leading up to the AIA's passage, members of Congress proposed alternative bills that would have replaced the on-sale bar with a publicity-based standard. In 2005, Representative Lamar Smith introduced the Patent Reform Act of 2005, which would have removed the on-sale bar entirely, invalidating patents only where "the claimed invention was patented, described in a printed publication, *or otherwise publicly known*." H.R. 2795, 109th Cong. (2005) (emphasis added). Senator Orrin Hatch introduced the same language in the Senate the following year. S. 3818, 109th Cong. (2006). In both 2008 and 2009, Senator Jon Kyl introduced bills that used different language to accomplish the same objective: replacing the on-sale bar with a publicity standard. These bills prohibited granting a patent where "the claimed invention was patented, described in a printed publication, or otherwise made available to the public (other than through testing undertaken

to reduce the invention to practice)." S. 3600, 110th Cong. (2008); S. 610, 111th Cong. (2009).

Moreover, advocates for these bills recognized that the changes they proposed would significantly modify existing law in order to create the result Petitioner advocates today. In a 2008 floor statement advocating for the passage of S. 3600, the Patent Reform Act of 2008, Senator Kyl described his bill as proposing "significant changes" through "amend[ing] the novelty condition of patentability by eliminating public use and the on-sale bar as independent bases of invalidity and instead impos[ing] a uniform test of whether art has been made available to the public." 154 Cong. Rec. 22,631 (2008). Senator Kyl described this "significant change" as "eliminating confidential sales and other secret activities as grounds for invalidity"—just what Petitioner now seeks.

Congress knew, then, that swapping the on-sale bar for a publicity standard was a potential patent reform, and Congress was aware of concrete proposals that would have enacted just such a sweeping change. Yet Congress *did not adopt* these proposals. Rather, "Congress several times considered, but rejected, the very changes to the on-sale bar [Petitioner] urges ... were actually made." Pet. App. 12a (O'Malley, J., concurring).

B. Instead, Congress Enacted Language Preserving the On-Sale Bar and Its Pre-Existing Meaning.

Instead of adopting language that would have replaced the on-sale bar with a publicity-based standard, Congress preserved the on-sale bar in the AIA by using the same "on sale" language already in

the U.S. Code and interpreted by this Court, which all sides recognized would preserve that term's pre-existing meaning.

Whether to preserve the on-sale bar was an openly contested issue during the debates leading up to the AIA's passage. During the House Committee on the Judiciary's consideration of the draft AIA, Rep. Lofgren proposed an amendment to remove the portions of an amendment from Rep. Smith that would have stricken the on-sale bar from the bill. Rep. Lofgren explained her opposition to the amendment this way:

> I have now heard strenuous concerns about the broader change from a wide range of stakeholders. In particular, they are concerned about the deletion of specific categories of prior art with well established meanings in case law and replacing those terms with a more ambiguous term ["]otherwise disclosed to the public["].

House Comm. on the Judiciary, *Markup of H.R. 1249, The America Invents Act* 101 (Apr. 14, 2011) ("*Markup*") (statement of Rep. Lofgren). Rep. Lofgren made clear that Rep. Smith's original proposal would have "up-end[ed] 100 years of patent law" by changing the definition of what actions can invalidate a patent (but that are nonetheless protected by the one-year grace period in section 102(b)). Simply put, Rep. Lofgren offered her amendment to retain not only the *words* "on sale," but also the *meaning* associated with those words, as they had been interpreted by this Court and the lower courts—indeed, that was the entire point of her amendment. Following her

statement, Rep. Smith announced his support for Rep. Lofgren's amendment and encouraged his colleagues to join him. *Markup* 102 (statement of Rep. Smith). Rep. Lofgren's amendment passed, thus blocking the attempt to remove the on-sale bar from the bill in Committee.[2]

This Committee proceeding demonstrates not only that the decision to include the on-sale bar in the AIA was a considered choice in Congress, but also that the stated rationale for preserving it was to maintain the meaning of a term well-established in the case law. Other contemporaneous statements from Senator Kyl demonstrate that he, too, believed that the language ultimately enacted in the AIA would have the effect of preserving the on-sale bar's existing meaning. In his minority statement in the Senate Committee on the Judiciary's report on the AIA bill, Senator Kyl urged the Senate to consider amending the bill "to remove subjective elements from patent law," including "patent-forfeiture provisions that apply only to non-public prior art." S. Rep. 111-18, at 60 (2009).

In short, all sides understood that whether to include the on-sale bar in the AIA was a live issue and that retaining the on-sale bar meant retaining its present meaning.

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[2] When the AIA ultimately reached a floor vote, Rep. Lofgren voted against it for reasons relating to other provisions not at issue in this appeal. That is irrelevant for tracing the progress of the bill through Committee or assessing the effect of the amendment Rep. Lofgren sponsored—which ultimately was adopted and became part of the AIA as enacted.

C. Isolated Floor Statements Do Not Change the Meaning of Enacted Language.

Instead of confronting the full picture of the legislative history outlined above, Petitioner focuses its legislative history argument on a single floor statement from a single legislator made just before the Senate voted on the AIA (which by that time contained both the "on sale" and "otherwise available to the public" provisions). *See* Petr. Br. 27-28. In this floor statement, Senator Kyl offered an aspirational interpretation of the AIA's on-sale bar language, asserting that the language as adopted would restrict the application of the on-sale bar to public sales only, not confidential or private sales. 157 Cong. Rec. S1370 (daily ed. Mar. 8, 2011) (arguing that "[t]he word 'otherwise' makes clear that the preceding clauses describe things that are of the same quality or nature as the final clause—that is, although different categories of prior art are listed, all of them are limited to that which makes the invention 'available to the public.'").

The floor statement even went so far as to say that the "new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated by the bill—an understanding on which the remainder of the bill is predicated." 157 Cong. Rec. S1370. Respectfully, there are two obvious issues with that statement. *First*, it suggests that the result for which Senator Kyl had advocated by proposing his own language *removing* the on-sale bar had, in fact, been brought about by language containing that bar, which he *opposed* in Committee precisely because it

would retain "patent-forfeiture provisions that apply only to non-public prior art." *See supra* at 14, quoting S. Rep. 111-18 at 60. That is an attempt to re-characterize a loss as a win—to make lemonade out of the lemons—when the proposal for replacing the on-sale bar with a publicity standard failed to gain traction. *Second*, the assertion that an individual legislator's preferred reading of the new section 102(a)(1) reflects "an understanding on which the remainder of the bill is predicated" is simply an overreach, and cannot speak for Congress's understanding as a whole. One member's understanding of the bill is just that: That member's understanding. Ample reason exists to doubt that this view of the AIA's meaning is the best interpretation of what Congress meant, particularly because Congress *rejected* the very reforms that were later asserted, in the floor statement, to be found in the AIA. Indeed, that interpretation is fundamentally inconsistent with the rationale Rep. Lofgren clearly articulated in offering her amendment, which was adopted by the Committee and enacted into law. *Markup* 101-102 (statement of Rep. Lofgren). All of this merely confirms what this Court has often recognized, that "floor statements by individual legislators rank among the least illuminating forms of legislative history." *NLRB v. SW Gen., Inc.*, 137 S. Ct. 929, 943 (2017).

Here, the far more illuminating—and indeed, dispositive—account of the legislative history encompasses the entire drafting, debate, and history of the on-sale bar provision of the AIA. The history of alternative bill proposals, the statements and debates about those bills, and the choices Congress ultimately made in adopting the AIA's final language all point in

one direction: that in the AIA, Congress chose to retain the on-sale bar, including its pre-existing meaning as interpreted by this Court.

CONCLUSION

For the foregoing reasons, this Court should affirm the decision of the Federal Circuit.

Respectfully submitted,

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October 16, 2018

No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., and
TEVA PHARMACEUTICALS INDUSTRIES, LTD.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE*, MASSACHUSETTS BIOTECHNOLOGY COUNCIL ("MASSBIO"), IN SUPPORT OF PETITIONER

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INTEREST OF MASSACHUSETTS BIOTECHNOLOGY COUNCIL ("MASSBIO")

Founded in 1985, Massachusetts Biotechnology Council ("MassBio") is a nonprofit association of more than 1,100 biotechnology companies, academic institutions, disease foundations, and other organizations involved in life sciences and healthcare, principally based or active in the Commonwealth of Massachusetts.[1] Of the more than 600 MassBio members that are life sciences companies, more than 88% have less than 250 employees worldwide, and 74% have less than 50. These small and midsize biotechnology companies depend on both strong patent rights and collaborations with other parties to maintain their ability to research, develop, and commercialize breakthrough medicines, and to ensure that patients around the world have affordable access to those new treatments.

MassBio opposes policies and laws that threaten patient access, limit innovation, or hurt the Massachusetts life sciences industry's competitiveness in the global economy. Because of the already numerous challenges faced by small and midsize biotechnology companies and the heavy reliance of these innovators on patent protection and collaboration, MassBio is

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[1] MassBio has no financial interest in any party or the outcome of this case. This brief was neither authored nor paid for, in whole or in part, by any party. Counsel of record received timely notice of the intent to file the brief under Supreme Court Rule 37. Petitioner consented to the filing of this brief through a blanket consent letter filed with the Clerk's Office on August 1, 2018. Respondent consented via e-mail received on August 23, 2018.

particularly concerned with the uncertainty and chilling effect established by the Federal Circuit's decision below regarding the types of transactions that may trigger the "on-sale" bar. MassBio believes that its industry experience and perspective will provide useful information for the Court's consideration of the question on appeal.

SUMMARY OF ARGUMENT

This case concerns a question of critical importance to the biotechnology and pharmaceutical industries: whether public disclosure of the existence of otherwise confidential pre-marketing agreements can be used to invalidate an innovator's patent. The Federal Circuit's decision below would categorically bar patents on the basis of any public disclosure of the *mere existence* of an agreement, rather than public disclosure of the invention itself. This holding ignores both the plain language of Section 102(a)(1), as amended by the Leahy-Smith America Invents Act (AIA), and the practical realities of what is often necessary to bring life-saving medicines to market.

The decision below improperly ignores Congress' express amendment of Section 102, holding instead that despite the plain language of the amended statute, as well as the wealth of consistent legislative history, Congress did not intend to change the meaning of the on-sale bar through the AIA. The Federal Circuit thus incorrectly applied the *pre*-AIA analytical framework for determining what constitutes a commercial sale under *pre*-AIA Section 102(b) to the amended

language of AIA Section 102(a)(1), essentially rendering the amendment meaningless.

In addition, notwithstanding statements by the panel and Judge O'Malley in her later concurrence in the denial of *en banc* review, the Federal Circuit's unusually categorical analysis in the decision below extends beyond the agreement at issue and purports to apply the amended on-sale bar to any instance where the *mere existence* of an agreement concerning an invention is disclosed.

This erroneous application of the on-sale bar to activities that fall outside of the plain meaning of the amended statute disproportionately affects small and midsize biotechnology companies that depend on both valid patents and the ability to access expertise they cannot efficiently build in-house by entering into pre-marketing collaborations with other companies in order to bring new drugs to market. In particular, where other federal statutes (such as the Securities Exchange Act of 1934) may require disclosure of the existence of these types of collaboration agreements, the Federal Circuit's decision effectively renders any such agreement as an invalidating sale under Section 102. This improper result forces innovator companies to either forgo their patent rights in order to fund the development of life-saving therapies or face the prospect of never making it to market at all.

Because the Federal Circuit's interpretation of AIA Section 102(a)(1) is in direct contravention of the plain meaning and intent of the amended statute, and has a particularly devastating effect on essential collaboration efforts within the biotechn-

ology and pharmaceutical industries, it should be rejected.

ARGUMENT

I. The Federal Circuit's Decision Ignores the Plain Language of the Amended On-Sale Bar Under AIA Section 102(a)(1)

In applying the on-sale bar to both *pre*-AIA and AIA patents the same way, the Federal Circuit has treated the AIA's amendment of Section 102 as an insignificant difference in phraseology rather than intentional, substantive change. This view violates basic principles of statutory construction and should be rejected.

Before the AIA, 35 U.S.C. § 102(b) (2000), stated (emphasis added):

> A person shall be entitled to a patent unless—
>
> . . .
>
> (b) the invention was patented ***or*** described in a printed publication in this or a foreign country ***or*** in public use ***or*** on sale in this country, more than one year prior to the date of the application for patent in the United States . . .

Thus, pre-AIA Section 102 could be read to list *four* categories of activities that would bar the issuance of a patent, each of which is separated by a disjunctive "or": (1) the invention was patented, (2) the invention was described in a printed publication, (3)

the invention was in public use, and (4) the invention was on sale. Alternatively, the statute could be read to list only *two* broad categories of activities, defined by different geographic limitations, where the second "or" (underlined below) separates activities taking place both domestically and abroad ("was patented or described in a printed publication") from activities taking place only domestically ("in public use or on sale"):

> (b) the invention was patented or described in a printed publication ***in this or a foreign country or*** in public use or on sale ***in this country***, more than one year prior to the date of the application for patent in the United States . . .

In 2013, Congress amended the language of Section 102 in 35 U.S.C. § 102(a)(1) (2011) to read as follows (emphasis added):

> A person shall be entitled to a patent unless—
>
> (1) the claimed invention was patented, described in a printed publication, ***or*** in public use, on sale, ***or*** otherwise available to the public before the effective filing date of the claimed invention . . .

Notably, the AIA amendment removed the geographic limitations from this provision. It also selectively removed some of the instances of the disjunctive "or," thus changing the language of the statute to provide for a list of *three* categories of qualifying activities, the third of which includes certain identified sub-categories: (1) the invention

was patented, (2) the invention was described in a printed publication, and (3) the invention was "in public use, on sale, or otherwise available to the public."

The added catch-all modifier to the third category —that a person would not be entitled to a patent if the claimed invention "was *otherwise* available to the public" before the effective filing date of the claimed invention—makes clear that all of the previously exemplified activities within the third category are included because they make the "claimed invention" "available to the public." *See Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008), *cert. denied*, 555 U.S. 1070 (2008) ("when a modifier is set off from a series of antecedents by a comma, the modifier should be read to apply to each of those antecedents"). This change in the text of Section 102 is consistent with the legislative history concerning the amendment. *See, e.g.*, 157 CONG. REC. S1370 (daily ed. Mar. 8, 2011) (statement of Senator Kyl) ("New section 102(a)(1) makes two important changes to the definition of non-patent prior art. First, it lifts current law's geographic limits on what uses, knowledge, or sales constitute prior art. And second, it limits all non-patent prior art to that which is available to the public. . . . Moreover, the fact that the clause 'or otherwise available to the public' is set off from its preceding clauses by a comma confirms that it applies to both 'public use' and 'on sale.' . . . Thus new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated by the bill—an understanding on which the remainder of the bill is predicated."); S. Rep. No. 110-259, at 9 (2008) ("Prior art also will no longer have any

geographic limitations; thus in section 102 the 'in this country' limitation as applied to 'public use' and 'on sale' is removed, and the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publicly available."); *id.* at 39 ("This Manager's Amendment also added the phrase 'otherwise available to the public' to 102 to make clear that secret collaborative agreements, which are not available to the public, are not prior art."). Thus, by amending Section 102, Congress manifestly intended that in order to trigger the on-sale bar, any "sale" must first make the "claimed invention" available to the public.

It is axiomatic that "[w]hen Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect." *Stone v. INS*, 514 U.S. 386, 397 (1995). This Court has repeatedly and consistently rejected interpretations of statutory language that ignores express Congressional amendment. *See Husted v. A. Philip Randolph Inst.*, 138 S.Ct. 1833, 1844-45 (2018) (rejecting reading of a statute that would make a second provision "redundant" and instead adopting a reading that "gives the new language added to the Failure-to-Vote Clause 'real and substantial effect'"); *Ross v. Blake*, 136 S.Ct. 1850, 1858 (2016) (rejecting interpretation of a statute where the lower court "acted as though the amendment —from a largely permissive to a mandatory exhaustion regime—had not taken place"); *Husky Int'l Elecs., Inc. v. Ritz*, 136 S.Ct. 1581, 1586 (2016) (in view of the amended language of the Bankruptcy Reform Act of 1978 adding "actual fraud" to the list that already included "a false representation," "[i]t is therefore sensible to start with the presumption that Congress

did not intend 'actual fraud' to mean the same thing as 'a false representation'"); *United States v. Quality Shores, Inc.*, 572 U.S. 141, 148 (2014) (rejecting exception to a statute where Congress amended and repealed that exception in 1950 and had not revisited the amendment since); *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241, 258-59 (2004) (rejecting view that 28 U.S.C. § 1782 applies only when adjudicative proceedings are "pending" or "imminent" because Congress had expressly amended the statute and eliminated the "pending" language, and the amendment's corresponding legislative history was consistent with this intended result); *Pierce Cty. v. Guillen*, 537 U.S. 129, 145 (2003) (rejecting interpretation of 23 U.S.C. § 409 where such "reading would render the 1995 amendment to § 409 (changing the language from 'compiled' to 'compiled *or collected*') an exercise in futility") (emphasis in original); *Babbitt v. Sweet Home Chapter of Cmtys. for a Great Or.*, 515 U.S. 687, 701, (1995) ("Given Congress' clear expression of the ESA's broad purpose to protect endangered and threatened wildlife, the Secretary's definition of 'harm' is reasonable.").

The Federal Circuit's opinion ignores this precedent and these fundamental principles and, as a result, intentionally conflates the analysis of pre-AIA Section 102(b) with AIA Section 102(a)(1). Although the court initially stated that it was "declin[ing] the invitation by the parties to decide this case more broadly than necessary," it then held that nothing about the changes to the statute or the corresponding legislative history overruled its prior, *pre*-AIA on-sale bar cases. *See, e.g.*, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1369-71 (Fed.

Cir. 2017). Thus, the Federal Circuit essentially acted as though the amendment "had not taken place." *Ross*, 136 S.Ct. at 1858.

The Federal Circuit's apparent explanation for its reluctance to interpret the AIA on-sale bar differently was that such an interpretation "would work a foundational change in the theory of the statutory on-sale bar." *Helsinn*, 855 F.3d at 1369. But statutory upheaval is precisely what Congress intended by enacting the AIA. *See generally* John Villasenor, *The Comprehensive Patent Reform of 2011: Navigating the Leahy-Smith America Invents Act*, Policy Brief No. 184, Brookings Institution (Sept. 2011) (the AIA "constitutes the most significant overhaul of the American patent system in decades"); 157 CONG. REC. S1362 (daily ed. Mar. 8, 2011) (statement of Senator Leahy) (the AIA provides "the first meaningful, comprehensive reforms to the nation's patent system in nearly 60 years"); 157 CONG. REC. S1495 (daily ed. Mar. 9, 2011); 157 CONG. REC. H4429 (daily ed. June 22, 2011). Where Congress has intentionally changed the language of the statute, there is no support for the Federal Circuit to rely solely on its own *pre*-AIA precedent and ignore Congress' express intent going forward.

More concerning, and despite its expressed reticence to make broad rulings, the Federal Circuit went even further than its pre-AIA precedent and misinterpreted certain floor statements by members of Congress, finding that "[i]n stating that *the invention must be available to the public* [Congress] evidently meant that *the public sale itself* would put the patented product in the hands of the public." *Helsinn*, 855 F.3d

at 1371 (emphasis added).[2] Based on these statements, the Federal Circuit then categorically held that "*after* the AIA, if *the existence of the sale is public*, the details of the invention need not be publicly disclosed in the terms of sale" in order for the sale to be invalidating. *Id.* (emphasis added).

Judge O'Malley attempted to soften this ruling in her later concurrence in support of the court's denial of *en banc* review. *See Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, App. Nos. 2016-1284,-1787 (Fed. Cir. Jan. 16, 2018) (denying *en banc*) (O'Malley, J., concurring), slip op. at 2-4. Citing back to the Federal Circuit's interpretation of the pre-AIA on-sale bar in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) (en banc), Judge O'Malley clarified that the "single factor" of the confidentiality of the sale "is not dispositive of the analysis." *Id.* at 3. Judge O'Malley also asserted that the Federal Circuit's decision had been limited, and that all it had held "was that the *particular* agreement at issue triggered the on-sale bar, in part—but not exclusively—because it was made public." *Id.* (emphasis in original). As support, Judge O'Malley noted that "Helsinn did not just disclose the fact that it had entered into a supply agreement with MGI" and further pointed to the Federal Circuit's discussion of other information that had been disclosed by the 8-K SEC filing, including that

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[2] The Federal Circuit similarly conflated cases concerning the "public sale" of an invention (whereby the *invention* is placed in the public domain) with instances where the invention is *kept secret*, but the existence of an otherwise confidential or private sale regarding the invention "is made public." *Helsinn*, 855 F.3d at 1369-70 (citing *Pennock v. Dialogue*, 27 U.S. 1, 19 (1829)).

a partially-redacted copy of the agreement itself had been included with the filing, that the agreement described the claimed drug formulation in detail, and that the agreement expressly contemplated the passage of title. *Id.* (citing *Helsinn*, 855 F.3d at 1361, 1364, 1366).

Judge O'Malley's reliance on the Federal Circuit's consideration of the additional information contained in the agreement that was disclosed by the 8-K filing appears directly contrary, however, to the Federal Circuit's own conclusion that, in the post-AIA world, "if the existence of the sale is public, *the details of the invention need not be publicly disclosed in the terms of sale*" in order for the sale to trigger the on-sale bar. *Helsinn*, 855 F.3d at 1371 (emphasis added). Thus, the very information that Judge O'Malley asserted was relevant to the case and "weighed strongly in favor of finding that the on-sale bar was triggered" is precisely what the Federal Circuit held is no longer relevant or necessary after the AIA if the existence of the sale itself is made public.

For all of the reasons above, the Federal Circuit's interpretation of AIA Section 102(a)(1) cannot be squared with the plain text of the amended statute or Congress' intent. It should be rejected.

II. SECRET COLLABORATIONS ARE VITAL TO INNOVATION AND DEVELOPMENT IN THE BIOTECHNOLOGY SPACE.

Correctly applying the AIA on-sale bar is vital to industries where pre-marketing transactions and collaboration are essential for success. The erroneous holding by the Federal Circuit that the AIA on-sale bar applies by disclosure of the *existence of* the sale

of an invention, rather than disclosure of the invention *by* a sale, has a particular chilling effect on innovation and collaboration within the biotechnology industry.

Biotechnology largely remains a small company industry, and the cost of biotech development is incredibly high. On average, it takes 10 to 15 years and approximately $2.6 billion to successfully bring a new drug to market—more than double the cost during the 1990's and early 2000's. *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20-33 (2016). Because many biotechnology companies operate without revenue, these costs represent significant challenges to companies seeking market entry. *See* Lisa Eckelbecker, *Biotech Startups Face Bigger Funding Challenges Than Other Industries*, TELEGRAM & GAZETTE, June 19, 2016, http://www.telegram.com/news/20160619/biotech-startups-face-bigger-funding-challenges-than-other-industries (noting the struggles of biotech companies in securing funding and one company's solution to "develop compounds up to the point that he could license something to a pharmaceutical company for the preclinical studies that lead to human testing").

Notwithstanding the funding challenges, however, small and midsize biotechnology companies have proven to be leaders in researching and developing breakthrough therapies and cures. *See* HBM Partners, *Trends in U.S. New Drug Approvals* (Jan. 2018) at 1 ("As in previous years, the majority (76%) of NMEs approved in 2017 originated from smaller or mid-sized biopharma companies, *i.e.* companies outside of the 30 largest biopharma firms."). Because "these

smaller companies often out-license their drug candidates or were acquired themselves before approval, the number of approvals under their name"—18 in 2017—actually "understates their important contribution to pharmaceutical innovation." *Id.* at 10.

As an example, Massachusetts is a leading state for biotechnology innovation, with over 35,000 jobs classified as Biotechnology Research and Development —more than any other state except California. *See* MassBio, *2018 Industry Snapshot*, at 4, http://files.massbio.org/file/MassBio-2018-Industry-Snapshot-FINAL-8-29-18.pdf. However, of the over 600 life sciences member companies of *Amicus*, at least 88% have less than 250 employees worldwide, and 74% have less than 50. Yet, Massachusetts researchers are currently researching and developing products for patients with over 400 different medical indications, including various cancers, neurological conditions, immune disorders, Alzheimer's, and diabetes. *Id.* at 25-26. As of 2018, Massachusetts's biotechnology drug development pipeline made up nearly one-fifth of the total U.S. drug pipeline. *Id.* at 24.

Because of the high cost of drug development and the limited resources available to most small and midsize biotechnology companies (as compared to pharmaceutical giants), these companies do not have the ability or resources to build internally all of the expertise and scale required to bring a new biotechnology product all the way to market. As a result, most biotechnology companies must rely on business partners to support their research and development. In the case of Helsinn, and many similarly-situated companies, entering into distribution or supply agree-

ments with a partner is necessary to obtain sufficient upfront funding to advance pipeline products through clinical trials and to gain access to critical expertise that these small companies cannot, as a practical matter, develop themselves. *See Helsinn*, App. Nos. 2016-1284,-1787 (O'Malley, J., concurring), slip op. at 12.

The Federal Circuit has previously held that, under pre-AIA Section 102(b), "[t]here is no room in the statute and no principled reason raised by the parties or any of the amici to apply a different set of on-sale bar rules to inventors depending on whether their business model is to outsource manufacturing or to manufacture in-house." *Medicines Co.*, 827 F.3d at 1378-79. The court appeared to acknowledge then the danger of "penalizing a company for relying, by choice or by necessity, on the confidential services" of another company in assisting with the development of life-saving medicines. *Id.* But the Federal Circuit's decision below walks squarely into that danger and has created a chilling effect that disproportionately harms small and midsize biotechnology companies.

Specifically, if a potential business partner is a public company (as many companies who possess the necessary resources and funding are), the partner may be required to disclose the existence of any such transactions under federal statutes such as the Securities Exchange Act of 1934. *See, e.g.*, 15 U.S.C. §§ 78m, 78o. This is precisely what Helsinn's partner, MGI Pharma, did in this case. *See* Pet.App.22a-24a; J.A. 255-406. The Federal Circuit's decision could translate any federally mandated disclosure of the existence of an agreement (without any meaningful

disclosure of the underlying invention that is the subject of the agreement) into a relinquishment of the innovator's patent rights. Put another way, the cost of doing business with a public company to develop and commercialize products would include giving up patent rights that otherwise would be protected. The Federal Circuit's improper interpretation of AIA Section 102(a)(1) thus chills collaboration and seriously hinders the ability of small companies to obtain the resources required to bring crucial medicines to market.

CONCLUSION

For the foregoing reasons, MassBio respectfully requests that this Court reject the Federal Circuit's interpretation of AIA Section 102(a)(1) and give proper consideration to Congress' intended changes to the scope of the on-sale bar.

Respectfully submitted,

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AUGUST 30, 2018

No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* THE NAPLES ROUNDTABLE IN SUPPORT OF NEITHER PARTY

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae The Naples Roundtable, Inc. is a 501(c)(3) non-profit organization whose primary mission is the exploration of ways to improve and strengthen the U.S. patent system. To achieve this goal, the Naples Roundtable supports the advanced study of both national and international intellectual property law and policy. The Naples Roundtable fosters the exchange of ideas and viewpoints among the leading intellectual property experts and scholars. It also organizes conferences and other public events to promote the development and exchange of ideas that improve and strengthen the U.S. patent system.

More information about the Naples Roundtable can be found on the organization's website: http://www.thenaplesroundtable.org. None of the Naples Roundtable, the individuals on its Board of Directors, or its counsel have any personal interest in the outcome of this case.

SUMMARY OF THE ARGUMENT

Amicus curiae submits this brief to focus on certain erroneous aspects of the Federal Circuit's methodology of statutory construction.

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1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae*, or its counsel, made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief.

The Federal Circuit's approach to statutory construction in this case illustrates the appeals court's failure to properly consider the explicit statutory purpose when construing the statute. Statutory text remains paramount, of course, but a statute's purpose cannot be overlooked when a court also examines other interpretative evidence in order to construe the statute.

In certain instances, Congress memorializes the purpose of legislation by including one or more "Sense of Congress" provisions. When Congress includes such a Sense of Congress provision, and when that Sense of Congress speaks directly to the interpretative question, then a court should consider this evidence of legislative purpose when construing the statute. This Court and other courts have done so in the past, recognizing that a Sense of Congress provision is highly probative evidence of the statute's legislative purpose. Indeed, because a Sense of Congress provision is part of the enacted legislation, it can be the strongest evidence of legislative purpose, as it is here.

Here, the Federal Circuit erroneously overlooked two explicit statutory Sense of Congress provisions, setting forth the purpose of the statute. By overlooking these explicit statements—that are part of the statutory text—the Federal Circuit's statutory analysis was incomplete and failed to account for the statutory objectives Congress sought to achieve when it passed the Leahy-Smith America Invents Act of 2011 ("AIA"), Pub. L. No. 112–29, 125 Stat. 284.

Within § 3 of the AIA are two Sense of Congress provisions that expressly state the objectives and

policies of the legislation. Behind the first-inventor-to-file regime, as embodied in revised 35 U.S.C. § 102, were Congress's expressly stated objectives of achieving both (1) "harmonization of the United States patent system" with those commonly used throughout the world and (2) "greater certainty regarding the scope of protection" provided by U.S. patents. AIA §§ 3(o), 3(p). Regarding the first objective, because the vast majority of patent applications filed outside the United States are filed in jurisdictions where secret commercialization is not regarded as prior art, the elimination of this category of prior art brings the U.S. patent system in line with the rest of the world. As for the second objective, Congress intended to create greater certainty in the patent system by making it easier to determine what is or is not prior art without resorting to expensive discovery. This second objective fits logically within the policy framework of a first-inventor-to-file system. Limiting prior art to information that is publicly known increases certainty about the validity of issued patents. Both legislative objectives are furthered by restricting the scope of prior art under § 102 to that which makes the claimed invention itself "available to the public."

Both congressional objectives were thwarted, however, by the Federal Circuit's incomplete statutory analysis. The appeals court did not cite, much less analyze, the Sense of Congress provisions, yet the court seemingly considered select arguments relating to legislative history. The court's incomplete analysis rests, in part, on its failure to consider the highly relevant Sense of Congress provisions.

ARGUMENT

I. The Correct Statutory Analysis Must Consider The Statute's Two "Sense Of Congress" Provisions

Congress's "authoritative statement is the statutory text, not the legislative history." *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 568 (2005); *see also Hoffman Plastic Compounds, Inc. v. NLRB*, 535 U.S. 137, 149–50 n.4 (2002); *Park 'N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 (1985) ("Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose."). For this reason, "the words of a governing text are of paramount concern, and what they convey in their context is what the text means." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 441 (2012). The obligation of the courts is thus to interpret the statute as written. *See Burrage v. United States*, 134 S. Ct. 881, 892 (2014) ("The role of this Court is to apply the statute as it is written—even if we think some other approach might accord with good policy.").

Even so, it is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *accord Sturgeon v. Frost*, 136 S. Ct. 1061, 1070 (2016). A word's meaning exists only in the context in which the word is used. *See Deal v. United States*, 508 U.S. 129, 132 (1993) (explaining the "fundamental principle of statutory construction (and, indeed, of language itself)" is that "the meaning of a word

cannot be determined in isolation, but must be drawn from the context in which it is used").

Legislative text is not always clear. *See, e.g., Utility Air Regulatory Group v. EPA*, 134 S. Ct. 2427, 2441 (2014) (noting that the Clean Air Act "is far from a *chef d'oeuvre* of legislative draftsmanship"); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 679 (1990) ("No interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship."). When the text is unclear or subject to multiple interpretations, courts will and should routinely consider other evidence, such as the legislative purpose of the statute.

This Court and others have regularly turned to statutory purpose to ensure that the correct interpretation is reached.

> We believe it fundamental that a section of a statute should not be read in isolation from the context of the whole Act, and that in fulfilling our responsibility in interpreting legislation, "we must not be guided by a single sentence or member of that sentence, but [should] look to the provisions of the whole law, and to its object and policy."

Richards v. United States, 369 U.S. 1, 11 (1962) (quoting *Mastro Plastics Corp. v. NLRB*, 350 U.S. 270, 285 (1956)); *see also* 1A Norman Singer & J.D. Shambie Singer, Statutes and Statutory Construction § 25:3 (7th ed. 2008) ("The statute should be construed according to its subject matter and the purpose for which it was enacted.").

On occasion, the objective and policy behind a statute are readily discernible because Congress explicitly stated as much in provisions titled the "Sense of Congress." A Sense of Congress provision will frequently state what Congress wanted to accomplish with the particular legislation. The current U.S. Code is replete with Sense of Congress provisions. *See, e.g.*, 2 U.S.C. § 1511(a); 5 U.S.C. § 9701(f)(1); 15 U.S.C. § 2221(l)(1); 21 U.S.C. § 1961(a).

This Court and other courts have turned to and relied on Sense of Congress provisions when interpreting statutes. In *Accardi v. Pennsylvania Railroad Co.*, 383 U.S. 225 (1966), the Court addressed whether a former employer had improperly denied World War II veterans their seniority rights guaranteed by the Selective Training and Service Act of 1940. The Court looked to the statute's language, noting that it "clearly manifests a purpose and desire on the part of Congress to provide as nearly as possible that persons called to serve their country in the armed forces should, upon returning to work in civilian life, resume their old employment without any loss because of their service to their country." *Id.* at 228. This "continuing purpose of Congress," as the Court observed, was further established by a Sense of Congress provision that spoke directly to the protection of employment rights to veterans returning to civilian life. *Id.* at 229.

Courts of appeals have similarly relied on Sense of Congress provisions when interpreting statutes. *See Hanson v. Espy*, 8 F.3d 469, 476 (7th Cir. 1993) (relying on a Sense of Congress provision to support the interpretation of the Disaster Assistance Act of 1988); *United States v. Ellis*, 714 F.2d 953, 955–56 (9th Cir. 1983) (relying on a Sense of Congress provision when interpreting the

Consolidated Farm and Rural Development Act of 1961). While a Sense of Congress provision may not always be controlling, it "can be useful in resolving ambiguities in statutory construction" and in reinforcing the meaning of the law. *State Highway Comm'n v. Volpe*, 479 F.2d 1099, 1116 (8th Cir. 1973).

Of course, a Sense of Congress provision does not generally create legal rights. The plain text of the Sense of Congress statement may use non-mandatory language, such as the word "should." *See, e.g., Monahan v. Dorchester Counseling Ctr., Inc.*, 961 F.2d 987, 994–95 (1st. Cir. 1992) (holding as non-binding a Sense of Congress that each state "should" review and revise its laws to ensure services for mental health patients); *Yang v. Cal. Dep't of Social Servs.*, 183 F.3d 953, 958–61 (9th Cir. 1999) (noting the Sense of Congress that Hmong and other Lao refugees who fought in Vietnam war "should" be considered veterans for purposes of receiving certain welfare benefits). Or the Sense of Congress provision is issued in a non-binding House or Senate Resolution. Even so, a sense of Congress provision is almost always a direct statement of legislative intent, having bicameral approval.

In some cases, such as with the AIA, a Sense of Congress provision is the best evidence of what the statutory text was intended to achieve. This Court has long examined the Sense of Congress when understanding the purpose of legislation and construing the terms of the legislation—even in the absence of a formal Sense of Congress provision. *See, e.g., Nat'l Cable Television Ass'n, Inc. v. United States*, 415 U.S. 336, 337 (1974) (relying on a Sense of Congress provision in the Independent Offices Appropriation Act of 1952); *see also Cameron Septic Tank*

Co. v. Knoxville, 227 U.S. 39, 50 (1913) (holding that it was "certainly the sense of Congress" that the Treaty of Brussels of December 14, 1900 did not affect the expiration of a U.S. patent); *McClurg v. Kingsland*, 42 U.S. 202, 207 (1843); *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 218 (1824). These examples and others confirm that the goal of statutory interpretation—understanding the meaning of the statute in the context of the statutory scheme and legislative purpose—can often be achieved by reference to a Sense of Congress provision.

In short, a Sense of Congress provision is a highly probative interpretative guidepost, which a court tasked with construing a statute should consider. Yet, the Federal Circuit entirely overlooked the Sense of Congress sections included in the AIA. Two Sense of Congress provisions in AIA § 3 speak directly to the issue of Congress's intent in adopting a first-inventor-to-file regime, as embodied in revised 35 U.S.C. § 102. As Petitioner explains, the Federal Circuit incorrectly limited its inquiry to select floor statements, to the exclusion of other statements, and at the same time diminished the importance of the statute's text. Pet. Br. 28–29.

Here, the two Sense of Congress provisions are perhaps the strongest evidence—beyond the text of § 102(a)(1)—about what Congress intended when it enacted the AIA. Instead of considering the Sense of Congress provisions, the Federal Circuit looked to—and dismissed the value of—certain floor statements by several members of Congress. The court's error was to look to only these floor statements and ignore the explicit objectives embodied in the Sense of Congress provisions.

The Federal Circuit's incomplete consideration of the interpretative evidence is an incorrect method of construing statutes. It leads to a misinformed view of legislative purpose. If this Court's interpretation of § 102(a)(1) considers interpretative evidence beyond that section itself, then this Court must reject the Federal Circuit's incomplete approach and must account for Congress's stated purposes for amending § 102, as set forth in the Sense of Congress provisions in the AIA.

II. The Federal Circuit Incorrectly Overlooked The Explicit Legislative Purpose Of The America Invents Act

In the present case, the Federal Circuit's interpretation of 35 U.S.C. § 102(a)(1), as enacted by the AIA, did not account for Congress's stated purpose for enacting the AIA. The purpose of the legislation is set forth in two Sense of Congress provisions. In the first, Congress stated its intent was to harmonize U.S. patent law with "the patent systems commonly used in nearly all other countries" by converting the U.S. patent system from a first-to-invent system to a first-to-file system. In the second provision, Congress stated its intent was to provide "greater certainty regarding the scope of protection." Both provisions underscore Congress's affirmative decision to eliminate the category of so-called "secret prior art," that is, any sales and uses that do not make available to the public "*the subject matter defined by a claim in a patent or an application for a patent*," as the term "claimed invention" is defined in 35 U.S.C. § 100(j).

A. Abrogating Non-Disclosing Sales and Uses as Prior Art is Consistent with Congress's Stated "Harmonization" Goal

One purpose of the AIA was to harmonize U.S. patent law with the patent systems of other major countries. This purpose is expressly stated in the AIA:

> SENSE OF CONGRESS. —It is the sense of the Congress that converting the United States patent system from "first to invent" to a system of "first inventor to file" will improve the United States patent system and promote harmonization of the United States patent system with the patent systems commonly used in nearly all other countries throughout the world with whom the United States conducts trade and thereby promote greater international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries.

AIA § 3(p).

Because Congress amended 35 U.S.C. § 102 with the express intention of harmonizing U.S. law with foreign patent systems, the Federal Circuit should have considered what the other major patent systems in the world require for prior art in order to determine which interpretation of amended § 102 best accords with Congress's intent in enacting the AIA.

To be clear, looking to non-U.S. patent jurisdictions to understand what Congress intended is not the type

of reliance on foreign law that is sometimes viewed skeptically. *Compare Atkins v. Virginia*, 536 U.S. 304, 316–17, n.21 (2002) (relying, in part, on an amicus brief by the European Union in a case about whether certain executions are prohibited by the Eighth Amendment), *with id.* at 322 (Rehnquist, C.J., dissenting) (writing separately "to call attention to the defects in the Court's decision to place weight on foreign laws . . . in reaching its conclusion").

Instead, examining non-U.S. patent systems is doing exactly what Congress did when it passed the AIA. It looked to what constituted prior art in the patent systems of the other major industrialized nations. It observed that most, if not all, nations require that prior art—and thus a prior art sale—must be known to the public. If the information is not known to the public, it is not prior art in the major non-U.S. patent systems. Knowing this, Congress included in the AIA its Sense of Congress provision indicating that its goal was to improve the U.S. patent system to be more like "the patent systems commonly used in nearly all other countries throughout the world with whom the United States conducts trade." AIA § 3(p). Accordingly, once the interpretative analysis of the AIA proceeds to the stage of considering statutory purpose and legislative history, it is entirely proper—and indeed necessary—to examine non-U.S. patent systems, as instructed by the Sense of Congress statement.

The top five national intellectual property offices are the European Patent Office, the Japan Patent Office, the Korean Intellectual Property Office, the State Intellectual Property Office of the People's Republic of China, and the United States Patent and Trademark Office. These five

intellectual property offices collaborate as the "IP5," which is "a forum of the five largest intellectual property offices in the world that was set up to improve the efficiency of the examination process for patents worldwide."[2] The national patent offices of the IP5 "handle about 80 per cent of the world's patent applications, and 95 per cent of all work carried out under the Patent Cooperation Treaty (PCT)."[3]

Examining the foreign patent systems would have revealed that in all major jurisdictions in the world, a sale or use of an invention does not constitute prior art unless the *invention itself* was available to the public. In none of these jurisdictions is it sufficient that the mere fact of the sale was public when the details of the claimed invention were not publicly available. If the Federal Circuit's decision is allowed to stand, the United States will be the outlier among the IP5, despite the AIA's stated objective of harmonizing this country's patent laws with the rest of the world. *See* Mark Schafer, *Note, How the Leahy-Smith America Invents Act Sought To Harmonize United States Patent Priority with the World, a Comparison with the European Patent Convention*, 12 Wash. U. Global Stud. L. Rev. 807 (2013).

1. Europe

Examination of patent applications in Europe is generally governed by the European Patent Convention, formerly known as Convention on the Grant of European Patents ("EPC"). The EPC is a multilateral treaty

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2. *See* About IP5 Co-Operation, http://www.fiveipoffices.org/about.html.

3. *Id.*

instituting the European Patent Organisation. The EPC established an autonomous legal system under which European patents are granted.[4]

The EPC requires that inventions claimed in European patents satisfy similar requirements as those in U.S. patents. Under the EPC, an invention must be novel, must involve an inventive step, and must be "susceptible to industrial application." EPC Art. 54, 56, 57. These three requirements are analogous to the novelty, nonobviousness, and utility requirements encoded in 35 U.S.C. § 102, § 103, and §§ 101 and 112, respectively.

Similar to U.S. law, Article 54(2) of the EPC defines what information constitutes "prior art" for purposes of novelty:

> The state of the art shall be held to comprise everything *made available to the public* by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

EPC 54(2) (emphasis added). Thus, the EPC expressly includes a requirement that information be "made available to the public" in order to be considered as state of the art, *i.e.*, "prior art."

The European Patent Office has issued examination guidelines that further state that non-public use or sale of

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4. The complete, regularly updated text of the EPC is available on the European Patent Office's website. https://tinyurl.com/EuropeanPatentConvention.

the invention does not constitute prior art. One section of the guidelines, reproduced below, highlights the European rule that the use of an invention must be public in order to qualify as a bar to patenting.

7.2.2 Agreement on secrecy

The basic principle to be adopted is that subject-matter has not been made available to the public by use or in any other way if there is an express or tacit agreement on secrecy which has not been broken.

In order to establish whether there is a tacit agreement, the division must consider the particular circumstances of the case, especially whether one or more parties had an objectively recognisable interest in maintaining secrecy. Important aspects in this regard are, inter alia, the commercial relationship between the parties (e.g. parent company and subsidiary, good faith and trust, joint venture or ordinary commercial transaction) and the exact object of the purported secrecy agreement (e.g. test specimens or parts for serial production).

A party alleging that subject-matter was not made publicly available due to an express or tacit agreement on secrecy must substantiate and, if contested, prove this allegation. A party alleging that an undisputed or proven agreement on secrecy was broken must substantiate and, if contested, prove this allegation.

European Patent Office, *Guidelines for Examination in the European Patent Office*, Part G IV-7.2.2 (Nov. 2017).[5] Thus, both the EPC and the European patent guidelines limit prior art to information that is known to the public.

2. China

The patent laws of China similarly require public use or sale of the invention in order for that activity to qualify as a bar to patenting.

Article 22.1 of the Patent Law of the People's Republic of China establishes that patents can issue only for those inventions that "are novel, creative and of practical use."[6] These requirements track the U.S. requirements of novelty, nonobviousness, and utility encoded in 35 U.S.C. § 102, § 103, and §§ 101 and 112, respectively. Article 22.2 defines "novelty" to "mean[] that the invention or utility model concerned is not an existing technology."

Article 22.5 then states: "For the purposes of this Law, existing technologies mean the technologies known to the public both domestically and abroad before the date of application." This provision thus establishes that an invention lacks "novelty" only if it was "known to the public."

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5. The EPO's *Guidelines for Examination in the European Patent Office* is available on its website. https://tinyurl.com/EPOGuidelines.

6. An English translation of the Patent Law of the People's Republic of China is available on the website of the State Intellectual Property Office of the People's Republic of China. *See* https://tinyurl.com/ChinesePatentLaw.

The examination guidelines for patent applications under Chinese law confirm this view. Section 2.1 of the Chinese guidelines, titled "Prior Art," provide:

> According to Article 22.5, the prior art means any technology known to the public before the date of filing in China or abroad. The prior art includes any technology which has been disclosed in publications in China or abroad, or has been publicly used or made known to the public by any other means in China or abroad, before the date of filing (or the priority date where priority is claimed).
>
> The prior art shall be the technical contents that are available to the public before the date of filing. In other words, the prior art shall be in such a state that it is available to the public before the date of filing and shall contain such contents from which the public can obtain substantial technical knowledge.
>
> It should be noted that technical contents in the state of secrecy are not part of the prior art. The state of secrecy includes not only the situation where the obligation to keep secret arises from regulations or agreements regarding confidences but also the situation where the obligation to keep secret arises from social customs or commercial practices, that is, from implicit agreements or understandings.
>
> However, if a person having the obligation to keep secret breaches the regulation, agreement,

> or implicit understanding, rendering the technical contents disclosed and making the technologies available to the public, these technologies shall form part of the prior art.

State Intellectual Property Office of the People's Republic of China, *Guidelines for Patent Examination* 171–72 (2010).[7]

The Chinese guidelines also explain that a "[d]isclosure by use means that by use the technical solution is disclosed or placed in the state of being available to the public." *Id.* at 173. The disclosure must be one through which "the relevant technical content is placed in such a state that the public can know it if they wish, disclosure by use can be established, and it is of no relevance whether the public had actually known it." *Id.* If "at an exhibition or demonstration of a product no explanation of the technical contents thereof is provided so that the structure and function or compositions of the product is not known to person skilled in the art, the exhibition or demonstration does not constitute a disclosure by use." *Id.*

3. Republic of Korea

Along the same lines, the patent laws of the Republic of Korea, *i.e.*, South Korea, require public disclosure in order to rise to the level of a patent-barring event. A non-public use or sale will not foreclose patenting of a novel invention in South Korea. *See* Jay Erstling & Ryan Strom, *Korea's Patent Policy and Its Impact on Economic Development:*

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7. https://tinyurl.com/ChinesePatentRules.

A Model for Emerging Countries?, 11 San Diego Int'l L.J. 441, 450–51 (2010) (describing the Korean Patent Act as "provid[ing] that an invention has novelty unless it is publicly known, used, or described in a 'distributed publication' or published through 'telecommunication means'").

Article 29 of the South Korea Patent Act sets forth the requirements of patentability. Article 29(1).1 prohibits patents on "[i]nventions publicly known or worked in the Republic of Korea or in a foreign country prior to the filing of the patent application." Patent Act (Act No. 950, as amended up to Act. No. 14112), art. 29(1) (2016) (S. Kor.).[8]

The guidelines applying South Korean patent law expand upon what is meant by "publicly known":

> A "publicly known" invention means an invention the contents of which have been known to an unspecified person without obligation of secrecy in the Republic of Korea or a foreign country prior to the filing of the application. The time of filing in the "prior to the filing of the application" refers to the exact point of time of filing, even to the hour and minute of the filing (if the invention is publicly known, the time is converted into Korean time). It does not mean the concept of the date of filing. "Unspecified persons" refers to the general public who does need to abide by secret observance duty.

8. An English translation of the Korean Patent Act is available on the website of the Korean Intellectual Property Office. https://tinyurl.com/KoreanPatentAct.

Korean Intellectual Property Office, *Patent Examination Guidelines* 208–09 (July 2013)[9]; *see also* Korean Intellectual Property Office, *Understanding the Patent Act of the Republic of Korea* 49 (2017) ("If an invention is disclosed to a person who is obligated to keep it confidential, it is not public knowledge.").[10]

Similarly, the Korean patent guidelines describe what is meant by "publicly worked" and when an invention cannot be patented because it has been "publicly worked."

> A "publicly worked" invention means an invention which has been worked under the conditions where the contents of the invention are to be publicly known or can potentially be publicly known in the Republic of Korea or a foreign country (Definition of "working" refers to the Patent Act Article 2). Also, "being public" means a situation where it is no longer kept in secret. So, even when a small fraction of inner part of an invention is kept in secret with regard to working of the invention, it shall not be considered as a publicly worked invention.

Korean Intellectual Property Office, *Patent Examination Guidelines*, *supra*, at 209. The thrust of the Korean patent law is the same as the other major jurisdictions—information must be publicly known in order to qualify as prior art.

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9. An English translation of the Korean Examination Guidelines is available on the website of the Korean Intellectual Property Office. https://tinyurl.com/KoreanPatentGuidelines.

10. https://tinyurl.com/UnderstandingKoreaPatentAct.

4. Japan

Finally, Japanese patent law applies the same approach to public use and sale as the other IP5 countries. Article 29(1) of Japanese patent law establishes the requirements for patentability:

> An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention, except for the following cases:
>
> (i) inventions that were publicly known in Japan or a foreign country prior to the filing of the patent application;
>
> (ii) inventions that were publicly worked in Japan or a foreign country prior to the filing of the patent application; or
>
> (iii) inventions that were described in a distributed publication, or inventions that were made publicly available through an electric telecommunication line in Japan or a foreign country prior to the filing of the patent application.

Patent Act (Act No. 121 of April 13, 1959, as amended up to Act No. 36 of May 14, 2014), art. 29(1) (1959) (Japan).[11] Japanese law uses the same phrases "publicly known" and "publicly worked" as South Korean patent law.

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11. An English translation of the Japanese Patent Act is available on website of the World International Patent Organization ("WIPO"). https://tinyurl.com/JapanesePatentLaw.

The guidelines for patent examination under Japanese law expand upon the meanings of "publicly known" and "publicly worked":

> 3.1.3 Publicly known prior art (Article 29(1)(i))
>
> "Publicly known prior art" means prior art which has become known to anyone as an art without an obligation of secrecy (Note).
>
> (Note) Prior art disclosed by a person on whom obligation of secrecy is imposed to another person who [is] not aware of its secrecy is "publicly known prior art" irrespective of the inventor's or applicant's intent to keep it secret. Generally, an article of academic journal would not be put in public view even if it was just received. Therefore, prior art described in the article is not "publicly known prior art" until the article is published.
>
> "Publicly known prior art" often become known in lecture, briefing session and so on generally. In this case, the examiner specifies the prior art on the basis of the matters explained in the lecture, briefing session and so on. In interpreting the explained matters, the examiner may use the matters derived by a person skilled in the art as a base for specifying "publicly known prior art" by considering the common general knowledge at the time of the lecture, briefing session and so on.

Japanese Patent Office, *Examination Guidelines for Patent and Utility Model in Japan*, Part III, ch. 2,

§ 3–3.1.3 (2018).[12] Again, the guidance of the Japanese Patent Office is no different than the guidance under the patent laws of Europe, China, and South Korea.

B. Abrogating Non-Disclosing Sales and Uses as Prior Art is Consistent with Congress's Stated Goal of Achieving Greater Certainty Regarding the Scope of Patent Protection

Another goal of the AIA was to increase certainty with respect to the scope of legal protection provided by issued patents. Congress stated its objective in a Sense of Congress provision in the AIA.

> SENSE OF CONGRESS.—It is the sense of the Congress that converting the United States patent system from "first to invent" to a system of "first inventor to file" will promote the progress of science and the useful arts by securing for limited times to inventors the exclusive rights to their discoveries and provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries.

AIA § 3(o).

With § 3(o) of the AIA, Congress sought to eliminate "secret" prior art that has, for decades, caused problems

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12. An English translation of the *Examination Guidelines for Patent and Utility Model in Japan* is available on the Japanese Patent Office's website. https://tinyurl.com/JapanesePatentGuidelines.

in the U.S. patent system. The Sense of Congress provision in § 3(o) embodies Congress's deliberate decision to eliminate an entire area of contention and inquiry regarding the scope of confidential sales and uses as prior art. As Senator Kyl stated before passage of the AIA, this change will have particular benefit in increasing certainty and reducing litigation discovery costs:

> Public uses and sales of an invention will remain prior art, but only if they make the invention available to the public. An inventor's confidential sale of his invention, his demonstration of its use to a private group, or a third party's unrestricted but private use of the invention will no longer constitute private [*sic*, prior] art. Only the sale or offer for sale of the invention to the relevant public or its use in a way that makes it publicly accessible will constitute prior art.
>
> The main benefit of the AIA public availability standard of prior art is that it is relatively inexpensive to establish the existence of events that make an invention available to the public. Under current law, depositions and litigation discovery are required in order to identify all of the inventor's private dealings with third parties and determine whether those dealings constitute a secret offer for sale or third party use that invalidates the patent under the current law's forfeiture doctrines. The need for such discovery is eliminated once the definition of "prior art" is limited to those activities that make the [invention] accessible to the public. This will greatly reduce the time and cost of

> patent litigation and allow the courts and the [USPTO] to operate much more efficiently.

157 Cong. Rec. S5319, S5319–21 (daily ed. Sept. 6, 2011) (statement of Sen. Kyl). This statement thus directly links Congress's stated objective in AIA § 3(o) of achieving greater certainty, with Congress's redrafting of 35 U.S.C. § 102(a)(1), limiting prior art to those sales and uses that make the invention itself available and known to the public.

Notably, the above statement of Senator Kyl refers to both categories of prior art—"offer for sale or third party use." 157 Cong. Rec. at S5320 ("Public uses and sales of an invention will remain prior art, but only if they make the invention available to the public."). The Federal Circuit's opinion below, however, dismissed Senator Kyl's floor statements because the specific examples of judicial decisions that the senator mentioned would be abrogated upon enactment of § 102(a)(1) were, according to the Federal Circuit, "public use" cases, not "sale" cases. App. 38a ("The floor statements do not identify any *sale* cases that would be overturned by the amendments." (emphasis in original)). It seems trivial to quibble about the specific cases cited by the Senator on the Senate floor when the statements explicitly and unambiguously referred to both categories of prior art—"[p]ublic uses and sales." 157 Cong. Rec. at S5320; *accord* 157 Cong. Rec. S1360, S1371 (Mar. 8, 2011) (statement of Sen. Kyl) ("A contrary construction of section 102(a)(1), which allowed private and non-disclosing *uses and sales* to constitute invalidating prior art, would be fairly disastrous for the U.S. patent system." (emphasis added)).

Thus, the AIA's abrogation of non-disclosing uses and sales as prior art in § 102(a)(1) was an intentional policy decision, one that achieves greater certainty in the scope of prior art and decreases litigation costs.

CONCLUSION

For these reasons, the Naples Roundtable respectfully submits that, to the extent the legislative purpose and legislative history are considered in construing post-AIA § 102(a), the Court must also consider the AIA's two Sense of Congress provisions as part of the statutory interpretation.

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August 30, 2018

No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA INC.
AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Respondents.

On Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF FOR *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.[1] Over the past decade, hundreds of new medicines have been approved by the Food and Drug Administration ("FDA"). In view of the risky biopharmaceutical research and development process, which has a significant failure rate, and the substantial requirements of the FDA to demonstrate safety and efficacy of new products, those results are not obtained cheaply. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $71.4 billion in 2017 alone.[2]

PhRMA seeks to foster innovation in new medicines, including by ensuring adequate patent protection to enable and incentivize its members' substantial investments in research and development. To those ends, PhRMA seeks to remove barriers that may

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[1] Pursuant to Rule 37.6, PhRMA affirms that no counsel for a party authored this brief in whole or in part, and that no such counsel or party or person other than amicus, its members, or its counsel made any monetary contributions intended to fund the preparation or submission of this brief. The parties consented to its filing.

[2] A complete list of PhRMA members is available at http://www.phrma.org/about/members (last visited Aug. 30, 2018). Members include Eisai Inc., Petitioner's U.S. marketing partner for Aloxi®, the product at issue in this case, and Teva US Specialty Medicines, a corporate affiliate of Respondents. Neither Eisai, Inc. nor Teva US Specialty Medicines contributed any money to fund the preparation of this brief.

arise in the nation's systems, including the patent laws, for protecting the intellectual property of its members — including as *amicus curiae* before this Court.

INTRODUCTION AND SUMMARY OF ARGUMENT

Congress amended the text of the statute defining "prior art," 35 U.S.C. § 102(a)(1), as part of the Leahy-Smith America Invents Act of 2011. The amendment affected what qualifies as prior art and what does not. One particular addition to the text, the phrase "or otherwise available to the public," specifically qualifies two categories already contained in the statute— "in public use" and "on sale." Those categories must now be read in a new light, limited by the new phrase, to encompass "in public use" and "on sale" only where that means that the claimed invention was available to the public through that public use or sale, and not where details of the claimed invention remained confidential.

The statute as amended requires that, to constitute prior art, a disclosure must put the public in possession of the claimed invention. Petitioner's private contract for the sale of its invention, at issue here, did not put the public in possession of the claimed invention because that contract was entered into with a third party bound by a promise of confidentiality as to specific features of that invention. Petitioner's subsequent patent, with claims drawn to the confidential features, therefore should not be barred.

Respondents have offered no credible alternative explanation of what change this particular amendment worked on the definition of prior art. Instead, Respondents throw up hollow arguments, such as

pressing old cases of this Court decided on several different versions of the statute going back more than two hundred years, and exaggerating Petitioner's construction of the amended statute to contrive "massive redundancies." Even though this Court's cases touching the old unqualified categories are of limited precedential value because the underlying statute itself has been amended, the Court's precedents do not support Respondents and, instead, show clear signs of pointing in the direction that the statute now clearly faces. Respondents' supposed "massive redundancies" construction results from an unreasonable reading of the statute and does not, on close inspection, create any redundancy.

The entire apparatus of the U.S. patent system has been recalibrated in accordance with the amended statute, explanations from Congress, and regulatory implementation by the United States Patent and Trademark Office, to effect what is rightly regarded as a sea change: the elimination of prior confidential activity as a determinant of patent rights. Under the new system, an inventor cannot invoke his or her own prior confidential acts to prevail in a priority contest against a rival claimant to a patent for the invention, but an inventor also need not fear that his or her own prior confidential acts would deprive him or her of a patent. The deliberate transformation of our patent system better aligns the United States with the rest of the world, promotes consistency and predictability in the administration of patent rights, and encourages early public disclosure of inventions in order best to promote the progress of science and useful arts.

ARGUMENT

I. Congress deliberately realigned the Patent Act's provisions on prior art to prevent the inventor's prior confidential activity from barring the ability to obtain a patent.

As explained in numerous other briefs in this case, the Leahy-Smith America Invents Act of 2011 was designed by Congress to transform the U.S. patent system from a first-to-invent to a first-inventor-to-file system.

The signal change required to accomplish this transformation was Congress' amendment of the definition of prior art in 35 U.S.C. § 102(a)(1) to eliminate conditions of patentability relating to confidential acts of the inventor before the filing of his patent application. *See* Pub. L. No. 112-29, § 3(b), 125 Stat. 285–86 (2011) (Leahy-Smith America Invents Act) (amending 35 U.S.C. § 102). That is, the courts and the Patent Office, in determining whether an inventor is entitled to the patent for a claimed invention, will no longer take heed of anything the inventor did confidentially before engaging the patent system. Public activities are another matter: an inventor's voluntary public disclosure of the claimed invention is prior art to a patent filed more than one year later. 35 U.S.C. § 102(b)(1). But an inventor who fails to file a patent application before another inventor independently conceives, files for, and claims the same invention can no longer invoke confidential evidence of his or her own invention, before the other's filing date, to attempt to bar the other's patent, because such confidential evidence did not apprise the public of the nature of the claimed invention. All that matters is

which filing date comes first.[3]

Similarly, where prior acts of public use or sale by an inventor do not apprise the public of the nature of the claimed invention due to, for example, confidentiality clauses, they also cannot be invoked to attempt to bar a patent. Because the claimed invention was not fully disclosed to the public, the subsequent issuance of a patent to that invention would not deprive the public of anything they already possessed. No party to this case is arguing that an open sale of a claimed invention that discloses to the public all aspects of the claimed invention and hides nothing of the invention's nature from the public cannot bar a subsequent patent. But a *confidential* sale, one that does not place the public in possession of the claimed invention, does not bar the patent under the statute as amended.

The amended statute must be interpreted to deprive an inventor of the right to rely on his or her own confidential pre-filing acts to try to bar another inventor's patent. It follows that it must also be interpreted to relieve the inventor of the burden of sacrificing his own patent due to his own confidential pre-filing acts. To do otherwise would frustrate Congress' transformation of the Patent Act into a first-inventor-to-file regime, with its exclusive reliance on disclosure to the public and filing of the patent application to define prior art. *See* Pub. L. No. 112-29, § 3(o), 125 Stat. 293 (2011) (expressing "sense of the Congress" that a first-inventor-to-file system better serves the constitutional purpose of the patent system—to "promote the progress of science and useful arts" with a limited

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[3] The Patent Act retains a provision for the inventor to challenge a fraudulent patent application that claims an invention "derived," i.e., stolen, from the inventor. 35 U.S.C. § 135 (2011).

right to exclude in exchange for full disclosure—by providing "greater certainty regarding the scope of protection" than the first-to-invent system).

The amendments to Section 102(a)(1) defining prior art share a unitary goal: to encourage public disclosure of inventions through engagement in the patent process, and thereby to build as large a body of knowledge as quickly as possible. The prohibition against an inventor's use of his or her own pre-filing confidential evidence of invention encourages early patent application filing, which eventually leads to public disclosure in a patent. The one-year grace period after public disclosure allows the inventor to gauge public opinion before committing resources to the patenting process. The elimination of the harsh aspects of the prior versions of the public-use and on-sale bars when they were applied to such uses or sales that did not make the claimed invention available to the public due, for example, to confidentiality agreements, frees the inventor from having to abandon the patent system in favor of continued secrecy after taking confidential initial steps toward commercialization.

II. Petitioner's correct interpretation of "otherwise available to the public" in amended Section 102(a)(1) does not create redundancy within the definition of prior art.

The amended statutory text lists three categories of prior art that bar issuance of a patent if the claimed invention was, before its effective filing date:

- "patented,"
- "described in a printed publication," or
- "in public use, on sale, or otherwise available to the public."

35 U.S.C. § 102(a)(1). Respondents argue that the phrase "otherwise available to public" in the third category must be interpreted to modify nothing at all because any other interpretation results in "massive redundancies," whether it is held to apply to the two subcategories of "in public use" and "on sale" in the third category , or to all three categories in their entirety. Br. in Opp. 3–4 (internal quotation marks omitted).

But Congress's use of "otherwise available to the public" in its amendment of Section 102(a)(1) has meaning that distinguishes, on the one hand, items in the other two subcategories of the third category, *i.e.*, acts of public use and acts of being on sale, when they provide details sufficient to make available to the public the claimed invention itself, from, on the other hand, such acts that do not provide sufficient detail to make the claimed invention available to the public. In the first instance, making "available to the public" details adequate to disclose the claimed invention means that the disclosure constitutes prior art that will not allow a later patent to remove that knowledge from the public domain. But, in the second instance, the less-than-full disclosure does not constitute prior art that bars issuance of a patent because the claimed invention, itself, has not become public knowledge.

As Petitioner explains in its principal brief, the phrase "otherwise available to the public" is properly construed to qualify the scope of "in public use" and "on sale" because all three are subcategories in the third category and grammar conventions show that the third category is set apart by the use of "or" from the other two categories. Pet. Br. 18–25. Respondents

argue that because this interpretation applies "otherwise available to the public" to "in public use," it must be redundant. Br. in Opp. 3.

Respondents are wrong in their claim that this interpretation creates redundancy. An item in public use might, nonetheless, conceal the claimed invention and therefore not be available to the public. Such uses are described by the Government as "secret public use." Gov't C.A. Br. 7–8. As Senator Kyl explained in his floor statement, Congress considered cases to be extreme when they treated public uses as prior art to void a patent even though the public use did not make the claimed invention available to the public. 157 Cong. Rec. S1371 (daily ed. Mar. 8, 2011) (statement of Senator Kyl) (citing, *e.g.*, *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881) (corset worn in public but concealed by clothing nevertheless a patent-barring public use)). Cases such as *Egbert* are "extreme" because they punish inventors by denying them patents for acts that, though committed in public, nevertheless still concealed from the public the nature of the invention. 157 Cong. Rec. S1371 (daily ed. Mar. 8, 2011). Congress intended to exclude such "extreme results" from the AIA definition of prior art and to limit the scope of prior art in public use that bars a patent to public uses that put the public in possession of the claimed invention before the patent application is filed. *Id.*

Applying "otherwise available to the public" to "on sale" similarly is not redundant; an item can be on sale and yet not make the claimed invention available to the public. The Federal Circuit recognized, for example, that whether the details of an invention are revealed to the public, or kept confidential, in the course of a sale was a "factor" in determining whether the sale triggers a bar under Section 102 prior to its

amendment by the Leahy-Smith America Invents Act. *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363, 1376 (Fed. Cir. 2016) (en banc). As discussed in the next section, this Court has never ruled on the question but has intimated that a secret public use should not be a bar. In any event, Section 102(a)(1), as amended, draws a distinction between sales that make the claimed invention "available to the public" and sales that do not. A sale which reveals to the public the details of the claimed invention bars a patent, while sales that withhold details do not, because they do not render the details accessible to the public.

In the present case, although the sale revealed to the public many details of the invention, it is undisputed that the sale required the parties to keep confidential at least one significant feature recited in the claim: the dosage. Pet. Br. 13. Thus the public, with full knowledge of the sale and all publicly-released details of the transaction, still would not have known what the invention was, because the claimed dosage and formulation were kept confidential.

III. This Court's precedents point toward limiting the "on sale" bar to public availability.

Respondents make much of the long history of the on-sale bar in this Court but fail to identify a single case in which this Court affirmed the invalidation of a patent in which a prior sale kept confidential from the public some facet of the claimed invention.

Prior versions of the statute were silent as to whether a confidential sale violated the on-sale bar, and this Court did not have occasion to resolve the issue. But in rendering decisions in numerous on sale and public use cases, this Court did suggest repeatedly that the bar against issuance of a patent is

triggered when the sale or use of the invention reveals the nature of the claimed invention to the public, because only then would issuance of the patent remove something from public knowledge.

This suggestion permeates the cases that Respondents cite, beginning with *Pennock v. Dialogue*, 27 U.S. 1 (1829), in which this Court applied the Patent Act of 1793. The patent in that case concerned an improved hose that was openly and publicly used such that the claimed invention would have been apparent to the public for years before patenting. *Pennock*, 27 U.S. at 3. The nature of the invention in *Pennock*—hose made more watertight by overlapping hose segments and riveting them together, rather than stitching them end-to-end—would have been immediately apparent to an observer; nothing in this Court's opinion or in the circuit court's opinion suggests otherwise. *See Pennock v. Dialogue*, 19 F. Cas. 171, 171 (C.C.E.D. Pa. 1825) (circuit court decision describing invention).[4] The Court explained that "the first inventor cannot acquire a good title to a patent; if he suffers the thing invented to go into public use, or to be *publicly* sold for use, before he makes application for a patent." *Pennock*, 27 U.S. at 23–24 (emphasis added). Thus even this nascent form of the on-sale bar tethered the sale to some public-facing disclosure. The next case Respondents cite, *Shaw v. Cooper*, quotes exactly this passage from *Pennock* in holding that the invention's "use by the public" before the patent application invalidated the patent. *Shaw*

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[4] Respondents assert that Pennock's hose joints "did not reveal the process" of their manufacture, Br. in Opp. 5, but offers no citation to the *Pennock* opinion or other explanation to substantiate this assertion.

v. Cooper, 32 U.S. 292, 318 (1833) (cited at Br. in Opp. 6).

Respondent's next two cases, *Kendall v. Windsor* and *Egbert v. Lippmann*, are inapposite to the present issue. *Kendall* concerned a trade-secret misappropriation by a non-inventor employee who had been pledged to secrecy. *Kendall v. Windsor*, 62 U.S. 322, 324–25 (1858) (cited at Br. in Opp. 6, 31). The trial court had found that "it did not appear any sale of the thing patented had been made." *Id.* at 327. The Court cited *Pennock* and *Shaw* merely to contrast the involuntary disclosure in *Kendall* from the voluntary, and patent-barring public use, in the earlier cases. *Id.* at 329–31. Because *Kendall* did not involve a voluntary public use, any broad pronouncements as to the nature of the public use or on-sale bar are dicta.[5] *Egbert*, as Respondents readily acknowledge, involved a gift of the invention to a recipient for use "without restriction or limitation." *Egbert v. Lippmann*, 104 U.S. 333, 336 (1881) (cited at Br. in Opp. 7, 21, 23). Nor did *Egbert* involve a sale. Its pronouncements touching the on-sale bar, like *Kendall*, are therefore dicta.

The final decision of this Court on which Respondents rely, *Pfaff v. Wells*, similarly took a cue from earlier decisions in expressing concern that an inventor should not be allowed "to remove existing knowledge from public use" by seeking a patent after a sale. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998)

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[5] This Court has expressed skepticism toward relying on "broad declarations" of legal principles expressed in its earlier decisions under obsolete versions of the Patent Act. *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 584 U.S. ---, sl. op. at 11 (2018).

(cited at Br. in Opp. 6, 7, 8, 31, 32). The Court's decision does not address whether the sale at issue was confidential as to the details of the claimed invention.

None of these cases addresses whether a sale of the invention, the terms of which sale bind the parties to confidentiality, bars a subsequent patent to the invention. Rather, the cases contain numerous suggestions that the touchstone for application of the bar is the public, non-confidential, and unrestricted disclosure of the claimed invention so that it is made available to the public. Congress, acting on those suggestions, amended the statute to require that issuance of a patent is barred by an earlier sale only if that sale revealed the claimed invention to the public, not if that sale was shrouded in confidentiality.

CONCLUSION

The judgment of the Court of Appeals should be reversed.

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INTEREST OF *AMICI CURIAE*

The R Street Institute[1] is a non-profit, non-partisan public-policy research organization. R Street's mission is to engage in policy research and educational outreach that promotes free markets as well as limited yet effective government, including properly calibrated legal and regulatory frameworks that support economic growth and individual liberty.

Engine Advocacy is a non-profit technology policy, research, and advocacy organization that bridges the gap between policymakers and startups, working with government and a community of high-technology, growth-oriented startups across the nation to support the development of technology entrepreneurship. Engine conducts research, organizes events, and spearheads campaigns to educate elected officials, the entrepreneur community, and the general public on issues vital to fostering technological innovation. Part of amplifying startup concerns includes highlighting the unique challenges small startups face when confronted with abusive, and typically opaque, patent litigation.

[1]Pursuant to Supreme Court Rule 37.3(a), all parties received appropriate notice of and consented to the filing of this brief. Pursuant to Rule 37.6, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of the brief. No person or entity, other than *amici*, their members, or their counsel, made a monetary contribution to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

Under 35 U.S.C. § 102, an inventor may not obtain a patent on an invention that has been "on sale" for more than a year. The question is whether, from this so-called on-sale bar, certain classes of sales should be exempted—sales under a confidentiality agreement, in Petitioner's view; and sales to those other than the ultimate customers, according to the government.

Neither class of sales should be exempted from the scope of § 102. To do so would open up an easily exploitable loophole in the on-sale bar that would undermine both patent law and the public welfare. Additionally, § 102 is best interpreted as consistent with basic property ownership principles, which dictate that all sales should be treated alike in view of the right to resell. For at least these reasons, the Court of Appeals should be affirmed.

1. Petitioner's theory that "secret sales" are outside the scope of § 102 is flawed because it would enable any inventor to circumvent the on-sale bar. The theory rests solely on a standard nondisclosure agreement between Petitioner and its buyer. Other inventors could attach the same sort of nondisclosure agreement to every sale of their inventions to avoid triggering the on-sale bar, allowing at least some inventors to delay filing their patent applications, potentially for years. Petitioner and some *amici* are incorrect in believing that the first-inventor-to-file system will mitigate this incentive for delay at least because, as this brief presents, there is a cheap and effective strategy for delaying filing as long as possible while still ensuring a position of being first to file.

There are at least two negative ramifications of widespread use of nondisclosure agreements to delay

patent filings. First, that strategy frustrates several basic premises of the patent system, in particular the time-limited patent term and the disclosure function of patents. Second, overuse of nondisclosure agreements ought not to be encouraged because it can impair other societally important work, such as research to discover safety or security concerns in consumer products. Interpreting § 102 so that it cannot be circumvented with nondisclosure agreements would avoid both of these problems.

2. Petitioner's and the government's theories of the case are also incorrect because they conflict with the principle against restraints on alienation. Because property may be resold freely, the act of placing an invention on sale inherently makes the invention available to the public: The inventor must accept that the invented product has entered the stream of commerce and now may reach any willing buyer. The inventor may contractually discourage resale and recover damages for breach, but has no power to prevent resale.

Neither Petitioner's nor the government's theory of the case is reconcilable with the inherently public nature of property sales. Both assume that an inventor can put an invention on sale and yet be unwilling to let some parties buy it—those outside the confidentiality agreement in Petitioner's view, and "ultimate customers" according to the government. As a result, neither theory is consistent with the notion that the buyer of a chattel is free to alienate it at will to any member of the public.

There are at least two reasons why it would be unwise to interpret § 102 as inconsistent with this traditional view of property rights. First, it is difficult to believe that a patent-specific understanding of sale is superior to common law property rules tested over centuries, especially

given that the on-sale bar has long been consistent with the freedom to alienate property. Second, as this Court reasoned in *Impression Products, Inc. v. Lexmark International, Inc.*, 137 S. Ct. 1523 (2017), statutory patent law ought to yield to property rights, especially at the point of sales. To conclude otherwise would wrongly allow for the Patent Act to intrude upon the statutory domain of property and commercial law.

The above considerations militate in favor of affirmance, but they also point to the larger significance of this case, which might otherwise appear to be no more than a squabble over the textual interpretation of a few words in § 102. Questions of whether inventors should enjoy an end-run around patent term limits and the disclosure requirement and whether intellectual property should displace physical property—these are questions that strike at the heart of the patent laws. This is an important case meriting scrutiny of all its implications, myriad and perhaps unexpected.

ARGUMENT

I. PETITIONER'S INTERPRETATION OF § 102 WILL HAVE HARMFUL CONSEQUENCES FOR THE PATENT SYSTEM AND PUBLIC WELFARE

It would be dangerous to agree with Petitioner's view that an inventor may place an invention on sale[2] without triggering the on-sale bar of 35 U.S.C. § 102(a)(1) merely by attaching a nondisclosure agreement to the sale. Should that view become the law of the land, inventors will almost certainly avail themselves of the opportunity to slap boilerplate nondisclosure agreements onto every product they sell, thereby allowing them to delay their patent filings and to enjoy an effectively extended patent term. That result would fundamentally undermine basic principles of patent law, and it would have the unexpected negative consequence of blocking valuable public safety and security research. These consequences are reason to disfavor Petitioner's interpretation of § 102.

A. EXEMPTING SECRET SALES FROM THE ON-SALE BAR WILL LEAD TO WIDESPREAD, INDISCRIMINATE USE OF NONDISCLOSURE AGREEMENTS

If Petitioner is correct that a nondisclosure agreement overcomes the on-sale bar, it is likely that such agreements will proliferate across all sales of products. Petitioner's nondisclosure agreement, which supposedly

[2] As a technical matter, it is not the "invention" being sold, but rather devices or goods that embody the invention. Nevertheless, for purposes of brevity and consistency with the statutory language, this brief uses the term "invention" as shorthand for "embodiment of the invention" where the context requires.

overcomes the on-sale bar, is nothing more than a standard form contract that others could easily replicate. *See* J.A. 107–09. And at least some courts have been willing to enforce the ubiquitous "shrink-wrap agreements" that prohibit study of products to reveal their internal workings. *See, e.g., Davidson & Assocs. v. Jung*, 422 F.3d 630, 639 (8th Cir. 2005); *Bowers v. Baystate Techs., Inc.*, 320 F.3d 1317, 1326 (Fed. Cir. 2003).[3]

The massive potential upside of this strategy is an extended patent term. Because a patent's term depends on "the date on which the application for the patent was filed," 35 U.S.C. § 154(a)(2), each day that the inventor can delay filing is an extra day of patent term. Those extra days can be significant. A single day on a pharmaceutical patent is worth $34 million for adalimumab (Humira, for rheumatoid arthritis)[4] and $24 million for ledipasvir/sofosbuvir (Harvoni, for hepatitis C),[5] for example. And in the software industry, opportunistic patent assertion entities often file their lawsuits "late in the patent term, precisely when litigation seems most

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[3]There are some cases "in conflict on the enforceability of anti-reverse-engineering clauses," although those predate *Davidson* and *Bowers*. Pamela Samuelson & Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 Yale L.J. 1575, 1626 (2002).

[4]*See* AbbVie Inc., Annual Report (Form 10-K), at 38 tbl. (Feb. 16, 2018); Initiative for Meds., Access & Knowledge, *Overpatented, Overpriced: Special Humira Edition* 6 (Sept. 2018), *available online*. Locations of authorities available online are shown in the Table of Authorities.

[5]*See* Gilead Scis., Inc., Annual Report (Form 10-K), at 50, 52 (Feb. 24, 2016) (computed based on $10.1 billion in U.S. sales and 88% product gross margin). Sales of Harvoni have decreased since then due to competing drugs and fewer patients requiring treatment. *See* Deena Beasley, *Gilead Profit Falls as Hepatitis C Sales Drop, Shares Down*, Reuters (May 2, 2017), *available online*.

abusive." Brian J. Love, *An Empirical Study of Patent Litigation Timing: Could a Patent Term Reduction Decimate Trolls Without Harming Innovators?*, 161 U. Pa. L. Rev. 1309, 1340–41 & tbl.7 (2013) (finding that non-practicing entities account for 61.2% of patent assertions within three years of patent expiry). Extra days of patent term can embolden this strategy.

If nondisclosure agreements allow inventors to sell their inventions without triggering the on-sale bar,[6] then inventors will not hesitate to sell their inventions for as long as possible until competition arrives, and only then seek patent protection. In many cases, this competition will be slow to arrive. The original inventor will naturally enjoy "the transient advantage inherent in being a first mover." *See Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 501 (2d Cir. 2004); Marvin B. Lieberman & David B. Montgomery, *First-Mover Advantages*, 9 Strategic Mgmt. J. 41, 42–47 (Summer 1988). And, as Judge Easterbrook explained, competitors would not want to sink costs into producing alternate products only to have the original inventor subsequently obtain a patent: "Fear of losing their investment may discourage rivals and enable the inventor to collect supra-competitive profits before obtaining a patent." *In re Mahurkar Double Lumen Hemodialysis Catheter Patent Litig.*, 831 F. Supp. 1354, 1369 (N.D. Ill. 1993) (Easterbrook, J., sitting by designation), *aff'd*, 71 F.3d 1573 (Fed. Cir. 1995).

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[6]This strategy may not seem amenable to simpler inventions that are harder to conceal even with a nondisclosure agreement. But inventors have a variety of techniques for concealing their inventions to render nondisclosure agreements effective. *See, e.g.*, S.R. Subramanya & Byung K. Yi, *Digital Rights Management*, IEEE Potentials, Mar.–Apr. 2006, at 31 (describing one class of such techniques).

Petitioner's theory of the case thus lays out a roadmap for any inventor to collect monopoly royalties for a period in excess of the statutory patent term: Sell the invention under boilerplate nondisclosure agreements, thereby avoiding the on-sale bar of § 102, and then file for patent protection as late as possible. It is difficult to believe that any inventor would not use this strategy to the fullest practicable extent.

B. Other Aspects of Patent Law Will Not Mitigate Incentives to Delay Patent Application Filing

Petitioner and several *amici* hypothesize that inventors will nevertheless file their patent applications early because of the new first-inventor-to-file rules, but there are several reasons to discount this hypothesis.

Prior to 2011, the United States followed a first-to-invent system by which the first inventor to arrive at an invention merited a patent, regardless of whether that inventor filed for patent protection before or after other competing inventors. *See* § 102(g) (2011). The America Invents Act changed that rule, awarding patent protection to the first to file a patent application, so long as that first filer arrived at the invention independently of other inventors. *See* 35 U.S.C. § 102(a)(2), (b)(2)(a).

Although the possibility of being displaced by a second comer is undoubtedly some incentive to file early under the first-inventor-to-file system, it is unlikely that this incentive will be sufficient to encourage all inventors to file early. Respondent Teva's brief (at 49–50) lays out several reasons for this conclusion, and another is worth mentioning.

To obtain as long a patent term as possible while also thwarting second inventors, an inventor need only file multiple repeated patent applications in secret[7] and then abandon them, retaining only the last one that predates any subsequent independent inventors. Taking the present case as an example, Helsinn could have filed a patent application on its invented drug in 2001 (when it first sold its invention to MGA), a duplicate of that application in 2002, another in 2003, another in 2004, and so on. If another company applied for a patent on the same drug in 2009, for example, Helsinn would then abandon all of these applications except for the one filed in 2008—just early enough to defeat the independent company's claim to patent priority but late enough to add seven years to the patent term.[8]

The aforementioned scheme is not especially costly—$1720 per application in fees, about the cost of printing two Supreme Court briefs. *See* 37 C.F.R. § 1.16(a), (k), (o). And practitioners already recommend that inventors file multiple rounds of applications as they improve their inventions.[9] It would require little effort for inven-

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[7] A patent application can be filed in secret under 35 U.S.C. § 122(b)(2)(B)(i). Doing so prevents the earlier applications from being prior art to the later ones. Also, the later applications would not claim priority to the earlier ones under 35 U.S.C. § 120, as doing so would cut off the later applications' patent term under § 154(a)(2).

[8] The above strategy presents several implementation problems, such as the timing of abandonments in view of the 18-month delay in publication of the independent company's applications, *see* § 122(b)(1)(A), and delaying examination during the waiting period. Patent attorneys will undoubtedly find solutions to these problems.

[9] *See, e.g.*, Kirk Cesari, *Filing Multiple Provisional Patents Per Non-Provisional*, Cesari-Reed (Feb. 6, 2016), *available online* (recommending filing multiple provisional patent applications "due to the first-to-file system the US now has"); Charles E. Van Horn, *Prac-*

tors to combine their existing multiple-application strategies with another strategy of selective abandonment,[10] thereby allowing those inventors to tack as much extra time as possible onto their patent term.

C. Use of Nondisclosure Agreements to Delay Patent Filings Will Thwart the Basic Aims of the Patent System

Proliferation of nondisclosure agreements that circumvent the on-sale bar would be devastating to fundamental principles of the patent system, in particular the limited duration requirement and the public disclosure function of patents.

The on-sale bar effectuates the basic principle that a patent is limited in duration. That patents are granted only "for limited Times" is a premise so fundamental that it is written into the constitutional authorization for patent grants. U.S. Const. art. I, § 8, cl. 8. But delayed filing at the front end equates to later expiration at the back end. In other words, "an inventor acquires an undue advantage over the public by delaying to take out a patent, inasmuch as he thereby preserves the monopoly to himself for a longer period than is allowed by the policy of the law." *Elizabeth v. Pavement Co.*, 97 U.S. 126, 137 (1878); *see also Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829) (noting that late filing of patent application can impermissibly "exclude the public from any farther use than what should be derived under it during" the

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ticalities and Potential Pitfalls When Using Provisional Patent Applications, 22 AIPLA Q.J. 259, 276 (1994) ("[I]t may be desirable to file a plurality of provisional applications in a period of a year . . . .").

[10] *Cf.* Van Horn, *supra* note 9, at 269 (describing another application of selective abandonment of provisional patent applications).

patent term). To prevent an inventor from acquiring this undue advantage, the on-sale bar forces the inventor to file within one year of the first offer for sale, thereby "confining the duration of the monopoly to the statutory term." *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998).

The on-sale bar also actualizes the public disclosure function of patents. The patent grant is understood to be a bargain, in consideration of which the inventor discloses the workings of the invention being patented: "The disclosure required by the Patent Act is 'the *quid pro quo* of the right to exclude.'" *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974)); *accord Universal Oil Co. v. Globe Co.*, 322 U.S. 471, 484 (1944); *see also Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989) (patent system is a "carefully crafted bargain"). Certainly nothing obligates disclosure of inventions through patent filings, but the inventor who "withholds his invention from the public, comes not within the policy or objects" of the patent system and thus may not enjoy the benefits of patent protection. *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1859). Section 102 implements this principle by forcing inventors to elect, within one year of first commercial use, between disclosing their inventions in patent filings or withholding them as trade secrets. *See Pennock*, 27 U.S. (2 Pet.) at 19. In the words of Judge Learned Hand, the inventor "must content himself with either secrecy, or legal monopoly." *Metallizing Eng'g Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 520 (2d Cir. 1946) (Learned Hand, J.).

Both the time limitation and the disclosure function of patents would be greatly undermined if nondisclosure

agreements sufficed to overcome the § 102(a)(1) on-sale bar. Imagine, for example, if Petitioner Helsinn had included its confidentiality terms in a package insert accompanying its invented drug. Helsinn could potentially have delayed filing its first patent application all the way until the first generic competitor's entry in 2011—ten years after Helsinn's initial sale to MGI and three years after FDA approval—all the while selling and profiting off of the drug. The public would bear the costs of the extended patent term and the delayed disclosure of the invention.

These public costs are not small. With regard to pharmaceuticals, for example, commentators report that "the average markup for patented drugs is nearly 400%," and "introducing generic competition can cause prices to fall to as little as 6% of the patent-protected price."[11] A month's supply of the cholesterol-lowering drug atorvastatin (Lipitor) cost about $165 while under patent, and $15 after the patent expired.[12] All these cost savings stand to be lost if inventors can extend their patents by delaying filing. Extending the patent on Lipitor, for example, would have cost Americans about $41 million *per day*.[13]

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[11] Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 Yale J.L. & Tech. 275, 284–85 (2016) (citing FDA and other studies); Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. Econ. Mgmt. Strategy 75, 83–84 & tbl.2 (1997) (finding that generic drug prices drop to below 50% of the patent-based price within 3 years of patent expiration).

[12] *See* W. Nicholson Price II, *Expired Patents, Trade Secrets, and Stymied Competition*, 92 Notre Dame L. Rev. 1611, 1622 & n.67 (2017).

[13] That number is computed as follows: The U.S. Census Bureau estimates the population of Americans aged 40 and over at 147

Patent applicants should not be able, by mere invocation of a nondisclosure agreement, to evade the fundamental patent *quid pro quo* of a limited-term monopoly in exchange for timely disclosure. Yet that is the very result to be expected should this Court endorse Petitioner's theory of secret sales. That theory would undermine the basic tenets of patent law, and it cannot be correct.

D. Over-Prevalence of Nondisclosure Agreements Will Impair Critical Research into Product Security, Safety, and Improvement

Besides subverting the basic aims of the patent system, a proliferation of nondisclosure agreements resulting from Petitioner's interpretation of § 102 would have the unintended consequence of undermining the practice of product research, a practice that confers important and substantial benefits upon the public welfare. Avoiding that unintended consequence is yet another reason not to impose Petitioner's desired limitation on § 102.

The practice of studying how a machine or product works is a time-honored tradition and a "fair and honest means" that works to the benefit of the public in multiple ways. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470,

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million in 2012. The CDC reports that 27.9% of that population used a cholesterol-lowering medication, and 20.2% of them used atorvastatin. *See* Qiuping Gu et al., Nat'l Ctr. for Health Statistics, Ctrs. for Disease Control & Prevention, *NCHS Data Brief No. 177, Prescription Cholesterol-Lowering Medication Use in Adults Aged 40 and Over: United States, 2003–2012*, at 1–2 (Dec. 2014), *available online*. Thus, 8.29 million Americans used atorvastatin in 2012. The difference between the on-patent and off-patent daily cost is $5 ($150 per month divided by 30 days), leading to a nationwide cost of $41.45 million per day.

476 (1974). Firms study their competitors' products to produce competing alternatives or to improve their current lines. This activity enriches the marketplace with competitive options and indeed "often leads to significant advances in technology." *Bonito Boats*, 489 U.S. at 160.

More importantly, product research is often the first step in protecting the public from serious harms or flaws in consumer products.[14] Computer scientists have reverse-engineered voting machines to demonstrate how those machines can be tricked into mistabulating votes during an election.[15] Analysis of computerized home automation devices such as thermostats has revealed that some of them mistakenly broadcast private information on the public Internet,[16] and some may be attacked and commandeered to spy on their owners.[17] Product research also enables consumers to engage in repairs. Online websites often disassemble products to provide step-by-step instructions for repairing everything from mobile phones to toothbrushes.[18]

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[14] *See generally* Trevor A. Thompson, *Terrorizing the Technological Neighborhood Watch: The Alienation and Deterrence of the "White Hats" Under the CFAA*, 36 Fla. St. U. L. Rev. 537, 543–60 (2009) (describing practices of software product vulnerability researchers).

[15] *See* Stephen Checkoway et al., *Can DREs Provide Long-Lasting Security? The Case of Return-Oriented Programming and the AVC Advantage*, Proc. 2009 Electronic Voting Tech. Workshop/Workshop on Trustworthy Elections, Aug. 10–11, 2009, at 3, *available online*.

[16] *See* Nick Feamster, *Who Will Secure the Internet of Things?*, Freedom to Tinker (Jan. 19, 2016), *available online*.

[17] *See* Grant Hernandez et al., *Smart Nest Thermostat: A Smart Spy in Your Home*, Proc. Black Hat USA 2014, Aug. 2–7, 2014, at 7, *available online*.

[18] *See iPhone X Teardown*, iFixit (Nov. 3, 2017), *available online*; Igor Orlovich, *Philips Sonicare HX6710 Teardown and Repair*, KuzyaTech (Nov. 3, 2013), *available online*.

Manufacturers are predictably unenthusiastic about researchers studying products either for competitive purposes or to expose flaws, and they frequently seek to preclude researchers from disclosing the results of their studies. One study found that 22% of computer security researchers had received legal threats arising out of their work.[19] Oracle's Chief Security Officer once condemned security research based on reverse-engineering, observing that Oracle's software license agreement prohibited it.[20] When Professor Ed Felten and student J. Alex Halderman discovered that music discs sold by Sony BMG were intentionally installing malicious software on consumer computers, they feared that Sony BMG might sue them for their research and so withheld their discovery for weeks—leaving millions of computers insecure and vulnerable to cyberattack.[21]

Should this Court approve Petitioner's claim that secrecy agreements avoid the on-sale bar and thus potentially allow inventors to delay filing of patent applications, the proliferation of secrecy agreements that will likely follow will add yet more tools that will help companies to suppress product research. This unintended negative side effect further militates against interpreting the on-sale bar of § 102 as Petitioner does.

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[19] Alexander Gamero-Garrido et al., *Quantifying the Pressure of Legal Risks on Third-party Vulnerability Research*, 2017 Proc. ACM SIGSAC Conf. on Computer & Comm. Security 1501, 1511.

[20] *See* Dennis Fisher, *Oracle CSO: You "Must Not Reverse Engineer Our Code"*, Threatpost (Aug. 11, 2015), *available online*. An anti-reverse-engineering agreement is sufficiently similar to a nondisclosure agreement for purposes of the analysis here, because both effectively prohibit revealing of the workings of an invention.

[21] *See* Deirdre K. Mulligan & Aaron K. Perzanowski, *The Magnificence of the Disaster: Reconstructing the Sony BMG Rootkit Incident*, 22 Berkeley Tech. L.J. 1157, 1198–99 (2007).

II. Principles of Property Rights Counsel Against Limiting the Scope of the On-Sale Bar, Contrary to the Views of Petitioner and the Government

Section 102 is best interpreted to encompass any sale or offer for sale, regardless of contractual conditions, the nature of the buyer, and whether the clause "or otherwise available to the public" modifies "on sale." This is because a buyer of an item has the basic property right to resell it. An inventor who puts an invention on sale, then, must embrace the fact that anyone may acquire the invention through resale, rendering the invention available to the public. Petitioner and the government both assume that inventors may constrain the universe of possible buyers, so their interpretations of § 102 are contrary to the freedom to alienate property.

Neither of their interpretations should be accepted for two reasons. First, the on-sale bar has always been consistent with property rights, and to render patent law inconsistent with centuries of experience would be inadvisable. Second, this Court has determined in a related context that patent law should not intrude upon the domain of property law; that determination should hold equally true in the context of § 102.

A. On-Sale Property Is Open to Resale and Therefore Inherently Available to the Public

1. A sale of property is a complete transfer of legal interest in the property from seller to buyer. One who places property "on sale," then, necessarily expresses a willingness to place the property irrevocably in the hands of the public.

Under traditional property law, a sale of property has at least two automatic effects. First, the seller loses all right to repossess the property—personal property must generally be held in fee simple, and servitudes are not permitted. *See* Thomas W. Merrill & Henry E. Smith, *Optimal Standardization in the Law of Property: The Numerus Clausus Principle*, 110 Yale L.J. 1, 17–18 (2000).[22] Second, the buyer has the unrestricted right to resell the purchased property, a right "tracing its lineage back to the 'common law's refusal to permit restraints on the alienation of chattels.'" *Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523, 1532 (2017) (quoting *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. 519, 538 (2013)). The item may be resold, transferred, or used in any other way desired regardless of the wishes of the original seller, an incident of the principle that property is owned "in total exclusion of the right of any other individual in the universe."[23]

Accordingly, a sale of property is inherently a public act. The item sold enters the public stream of commerce, such that anyone may acquire it at the right price. Certainly a seller may enter a private contract with a buyer in an effort to constrain the buyer's resale or disclosure of the item, and may recover money damages for a violation. But if the buyer further sells the item downstream, the seller has no recourse to recover control over the item.[24]

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[22] It is undisputed that title was transferred in fee simple in this case; it should be left to future courts to decide the treatment of more exotic transfers, such as life estates or sales subject to security interests.

[23] 2 William Blackstone, *Commentaries on the Laws of England* *2 (1765).

[24] *See* Hal M. Smith, *Title and the Right to Possession Under the Uniform Commercial Code*, 10 B.C. Indus. & Com. L. Rev. 39, 47

And a downstream buyer can overcome any contractual limitation on the original buyer by offering a price sufficient to overcome the cost of breach. So even if an inventor is willing to sell directly only to one specific buyer, the sale of the invention necessarily makes that invention available to the public.

An unconsummated offer for sale equally renders an invention available to the public. Inventors who place their inventions "on sale" must accept the consequence that their sold inventions, being property, will be exposed to the public market by operation of property law. Because an offer for sale is one that a third party buyer can accept at the snap of a finger, *see* U.C.C. § 2-206 (2002), an inventor would not make an offer for sale without being willing to accept the consequences of acceptance and a completed sale. Should an inventor be unwilling to accept those consequences, the inventor has a host of alternate forms of transactions—selling marketing rights or patent licenses, for example[25]—that do not carry the public consequences of a sale. An offer to sell, even if never accepted, evinces the inventor's willingness to cede control over the invention, to release it to the whims of the open market, and thus to make the invention available to the public.

2. Neither Petitioner Helsinn's nor the government's interpretation of § 102 is consistent with the above ordinary operation of property rights. Helsinn argues (at 14) that the presence of a confidentiality agreement attached to sale of an invention means that the invention

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(1968) ("Once the original buyer obtains title, he has the power by transfer to a subsequent good faith purchaser to cut off the seller's reclamation right.").

[25] *See In re Kollar*, 286 F.3d 1326, 1334 (Fed. Cir. 2002) (discussed *infra* p. 22).

was not "available to the public." But the buyer, MGI Pharma, was free to resell what it had bought; Helsinn may have had a contractual remedy but no way to rewind the resale.[26] Helsinn's interpretation of "on sale" thus gives contract law improper primacy over property law and supposes that the confidentiality contract still gave Helsinn "control" over property it had sold.

A similar flaw is present in the government's theory (at 26) that only sales to "expected ultimate customers" qualify for the on-sale bar. MGI was free to resell to said "ultimate customers" at its pleasure, again facing at most damages for breach. The government's theory only makes sense if Helsinn could restrain MGI from alienating its property to those ultimate customers—something that traditional property law does not allow.

Fundamentally, both Petitioner and the government presume that an inventor who sells an invention can intend for the invention to reach the hands of some buyers but not others. That presumption is irreconcilable with the right to alienate property.

B. The On-Sale Bar Has Been and Should Be Interpreted as Consistent with Free Alienability of Property

Certainly Congress is permitted to draft § 102 in a way that clashes with traditional property rights, but there are several reasons to believe it did not. Foremost among these is that property law is a well-seasoned jurisprudence that ought not to be rewritten in a patent-exceptional manner.

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[26] It is irrelevant that Helsinn had not delivered the invention to MGI; one can resell title to purchased property before delivery.

The right to alienate property is among the most ancient rules in the already-ancient law of property. Rules against sellers' dead-hand control over alienated property trace back at least to the English 1290 statute *Quia Emptores*, which permitted unconditional assignment of land but prohibited a partial alienation practice called "subinfeudation."[27] Sir Edward Coke in 1628 famously described restraints on alienation as "against Trade and Traffique, and bargaining and contracting between man and man." 1 Edward Coke, *Institutes of the Lawes of England* § 360, at 223b (1628), *available online*; *see also id.* § 334, at 205b ("Conditions [on alienated property] bee not favoured . . . ."). Numerous American commentators have agreed,[28] and courts have uniformly followed the rule against restraints on alienation.[29] This Court recently described the principle as one of "impeccable historical pedigree." *Impression Prods.*, 137 S. Ct. at 1532 (quoting *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. 519, 538 (2013)).

The on-sale bar has long adhered to these basic notions of property ownership, defining the transfer of alienable title to the invention as the critical date when the bar begins to run. Courts have construed "on sale"

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[27] *See* Quia Emptores, 1290, 18 Edw. 1, c. 1 (Eng.); Ronald B. Brown, *The Phenomenon of Substitution and the Statute Quia Emptores*, 46 St. Louis U. L.J. 699, 708–11 (2002) (explaining subinfeudation as an alienation of property in which the seller continued to demand feudal duties from the purchaser).

[28] *See, e.g.*, 4 James Kent, *Commentaries on American Law* *129, 131 (4th ed. 1840), *available online*; John Chipman Gray, *Restraints on the Alienation of Property* § 259, at 244 (2d ed. 1895), *available online*.

[29] *See* Richard E. Manning, *The Development of Restraints on Alienation Since Gray*, 48 Harv. L. Rev. 373, 403 & nn.127–128 (1935) (citing cases).

under § 102 with respect to the Uniform Commercial Code, which defines "sale" as "the passing of title from the seller to the buyer for a price." U.C.C. § 2-106 (2002); *see Meds. Co. v. Hospira, Inc.*, 827 F.3d 1363, 1373 (Fed. Cir. 2016) (en banc) (citing *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001)). Based on this definition, the Federal Circuit has held that a sale under § 102 is an agreement "to give and to pass rights of property for consideration," and after property is sold, the buyer "normally owns it outright." *Meds. Co.*, 827 F.3d at 173 (quoting *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1361 (Fed. Cir. 2010)); *id.* at 1374 (quoting *Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1378 (Fed. Cir. 2003)); *see also In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985) ("It is well settled that a sale is a contract between parties to give and to pass rights of property . . . .") (citing 77 C.J.S. *Sales* § 1 (1952)).

The extensive reach of the on-sale bar confirms § 102's relation to property alienability. Sales of products where the nature of the invention is hidden or not discernible still trigger the on-sale bar because the relevant event is not the buyer's knowledge of the invention but rather the seller's giving up control over the invention to another; the bar applies "regardless of how little the public may have learned about the invention." *Metallizing*, 153 F.2d at 520;[30] *see Egbert v. Lippmann*, 104 U.S. 333, 336 (1881). Similarly, sales by third parties other than the inventor also start the on-sale bar clock, *see Evans Cooling Sys.*,

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[30] Though *Metallizing* dealt with use rather than sale, its "forfeiture" principle has been applied to the on-sale bar. *See, e.g.*, *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1147 (Fed. Cir. 1983).

Inc. v. Gen. Motors Corp., 125 F.3d 1448, 1454 (Fed. Cir. 1997); *Abbott Labs. v. Geneva Pharm., Inc.*, 182 F.3d 1315, 1318 (Fed. Cir. 1999); *Caveney*, 761 F.2d at 677, as third-party sales equally place the invention on the open market.

Notably, too, the public nature of property sales explains decisions holding the on-sale bar *not* applicable. In *Elizabeth*, an inventor's experimental use of a new type of pavement was held not to affect his patent rights because, among other things, the inventor "did not let [the invention] go beyond his control" and "kept it under his own eyes." 97 U.S. at 136. *In re Kollar* explained that licensing of patent rights or manufacturing rights does not constitute a sale under § 102, *see* 286 F.3d 1326, 1334 (Fed. Cir. 2002); this is justifiable because a license, unlike sold property, is not further alienable to others. *See Troy Iron & Nail Factory v. Corning*, 55 U.S. (14 How.) 193, 216 (1853); *Cincom Sys., Inc. v. Novelis Corp.*, 581 F.3d 431, 436 (6th Cir. 2009) (noting "special rule" of non-assignability of patent licenses). That an inventor's retention of control does not invoke the on-sale bar indicates that an inventor's relinquishment of control—a sale—is the hallmark of invoking the bar.

It seems unlikely that Congress would intend to upend the time-honored rules of property law despite decades of consistency. It would furthermore be imprudent to ignore centuries of jurisprudence for the sole benefit of certain inventors. History thus teaches that the proper understanding of the on-sale bar of § 102 is to treat the act of placing an invention on sale as an inherently public act.

C. The On-Sale Bar Should Not Intrude upon the Statutory Domain of Property Law

A patent-exceptional notion of property sales would also contradict the logic of *Impression Products*, that the domain of patent law does not extend to redefining commercial sales.

The question in *Impression Products* was whether a patent owner could use a so-called "conditional sale" in order to prevent purchasers of inventions from engaging in resale or other uses of their purchased property. *See* 137 S. Ct. at 1531. In answering this question in the negative, the Court explained that the sale of property "marks the point where patent rights yield to the common law principle against restraints on alienation." *Id.* at 1526. The traditional property right "to use, sell, or import an item exists independently of the Patent Act." *Id.* at 1534. Any residual rights over the sold property were "a matter of the contracts with [the] purchasers, not the patent law." *Id.* at 1533. Once a sale had occurred, standard property law took effect, and it was no longer the place of patent law to interfere.

Certainly *Impression Products* dealt with the exhaustion doctrine and not the on-sale bar, but its treatment of the relationship between patent law and property can and should be viewed more broadly. The driving proposition, that patent law should not interfere with the statutory domain of commercial and property law, has been long appreciated in legal scholarship. *See* John F. Duffy & Richard Hynes, *Statutory Domain and the Commercial Law of Intellectual Property*, 102 Va. L. Rev. 1, 7–9 (2016). As then-Professor Easterbrook proposed, "unless the statute plainly hands courts the power to

create and revise a form of common law"—§ 102 obviously does not—"the matter in question [is] outside the statute's domain," and courts ought to look "to whatever other sources of law might be applicable." Frank H. Easterbrook, *Statutes' Domains*, 50 U. Chi. L. Rev. 533, 544 (1983). Insofar as *Impression Products* concluded that the exhaustion doctrine of patent law should not redefine common law rights of property ownership, the on-sale bar should not redefine property rights either.

Intellectual property is important, of course, but in the end it cannot compare to the importance of traditional, tangible, physical property. In deciding how to interpret the on-sale bar under § 102, it makes the most sense for patent law to follow property law, not the other way around.

CONCLUSION

For the foregoing reasons, the decision of the Court of Appeals should be affirmed.

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October 2018

No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A.

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,
TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Respondents

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR *AMICUS CURIAE* CONGRESSMAN LAMAR SMITH IN SUPPORT OF PETITIONER

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August 23, 2018

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INTEREST OF AMICUS CURIAE [1]

Amicus Curiae Congressman Lamar Smith served as Chairman of the Committee on the Judiciary of the U.S. House of Representatives during the pendency of the Leahy-Smith America Invents Act. He was the lead sponsor of the bill and managed its consideration in the House. *Amicus Curiae* has no personal or financial interest in the parties to this litigation or in the outcome of this specific case. His sole interest in this appeal is that 35 U.S.C. § 102(a)(1) be interpreted in a manner faithful to the legislative text.

SUMMARY OF THE ARGUMENT

An inventor's sale to a third party, *in which the subject matter defined by the claims of the inventor's patent must be kept confidential*, cannot invalidate patent claims under the America Invent Act's new 35 U.S.C. § 102(a)(1). The provisions of § 102 that were repealed under the Act had formerly provided that such a "loss of right to patent" might be triggered by such inventor-attributable "on sale" activities. With the repeal of all such "loss of right to patent" provisions, new § 102 now contains only a requirement for "novelty" over "prior art." However, under new § 102(a)(1), the requirement for "novelty" is fully satisfied unless the subject matter defined by a claim becomes "available to the public." In this appeal, confidentiality obligations prevented the required public

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[1] This brief was not authored, in whole or in part, by counsel for any party. No person or entity other than *Amicus curiae* or his counsel of record made a monetary contribution to the preparation or submission of this brief. Each party has consented to the filing of this brief.

disclosure of the details of the invention from taking place. Thus, under the Act, the inventor's patent claims here are not invalid under § 102.

Congress altered the patent law dramatically with the American Invents Act, including in ways that impact this appeal. The changes were based on a set of recommendations from the National Research Council of the National Academies. At the urging of the NRC, Congress abandoned the first-to-invent principle, a bedrock of patent statutes for 175 years. Congress did so in large measure because that principle *had complicated the law on "prior art" and fostered the creation of numerous "loss of right to patent" provisions*. Moreover, such features of U.S. patent law placed the United States out of step with every other country in the world.

Congress based its new patent statute on the first-inventor-to-file principle in order to fashion a simplified and internationalized set of conditions for patentability in new §§ 102-103. This allowed Congress to enact a new § 102 limited to a requirement for novelty. It further allowed a dramatic clarifying and streamlining of the definition for prior art.

The changes to the law arising from the drafting of new § 102's "prior art" provision involved retiring the phrase "known or used" from repealed § 102(a)'s definition of prior art, notwithstanding that this phrase had been used to define "prior art" in every patent statute since 1790. It was replaced with an *alter ego* term, "available to the public."

This new terminology is used internationally to define prior art, in part by excluding confidential or otherwise secret subject matter from qualifying as prior art. It is also used judicially in the United

States to explain that subject matter could qualify under repealed § 102(a) as "known or used" only when *publicly disclosed*. Most significantly, the term "available to the public" in new § 102(a)(1) now functions as a terminal qualifier limiting prior art arising from "in public use" or "on sale" activities to what renders the subject matter defined by the patent claims available to the public.

Thus, to the end of a simpler and more internationalized patent system, the new statute both eliminated "loss of right to patent" provisions in which inventor-attributable activities might bar a patent under old § 102 *irrespective of whether the subject matter defined by the claims was made publicly available* and similarly limited the "novelty" bar to patenting such that the subject matter defined by a claim must now be available to the public. The simplicity of the new statute makes it difficult to read in any other way.

Even if it could be so read, there would be no justification as a matter of patent policy to do so. Congress determined that preserving patentability so long as the subject matter of a patent claim had not been publicly disclosed would provide a continuing incentive to disclose novel and non-obvious subject matter. In contrast, the repealed law operated to encourage continued secrecy once the right to patent had been forfeited though "on sale" activities attributable to the inventor, even if secret. The America Invents Act aligns with the patent system's constitutional purpose to encourage disclosure and, thus, promote progress in useful arts by replacing that incentive for secrecy with a continuing incentive to disclose.

ARGUMENT

I. Congress Repealed 35 U.S.C. § 102 And Replaced It With A First-Inventor To File Statute Eliminating Each Of § 102's Bars To Patenting Except For Lack Of Novelty Over Prior Art.

A. The America Invents Act Made Historic Reforms To U.S. Patent Law By Adopting The First-Inventor-To-File Principle.

The America Invents Act was the product of a six-year congressional effort[2] to simplify and internationalize U.S. patent law.[3] The magnitude and importance of the changes made to the U.S. patent system through the Act were virtually without precedent in the more than 200-year history of the U.S. patent law.[4]

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[2] Prior to the introduction of the America Invents Act in 2011, Congress considered similar bills beginning in 2005, the most significant of which were the Patent Reform Act of 2005, H.R. 2795, 109th Cong.; Patent Reform Act of 2007, H.R. 1908, 110th Cong.; Patent Reform Act of 2008, S. 3600, 110th Cong.; and Patent Reform Act of 2010, S. 515, 111th Cong.

[3] Robert A. Armitage, *Leahy-Smith America Invents Act: Will It Be Nation's Most Significant Patent Act Since 1790?*, Washington Legal Foundation Legal Backgrounder Vol. 26, No. 21 (September 23, 2011), available at https://www.wlf.org/wp-content/uploads/2018/08/09-23-11Armitage_LegalBackgrounder.pdf.

[4] See generally, Robert A. Armitage. *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q.J. 1 (2012), available at

The motivation for pursuing such an ambitious set of reforms to the patent law in a single bill arose from a set of sweeping recommendations from the National Research Council of the National Academies of Science. These recommendations were made in a 2004 report that was the product of the NRC's four-year study of the patent system.[5]

The NRC recommended eliminating a fundamental aspect of the U.S. patent law that had been in effect since at least the Patent Act of 1836.[6] It proposed to eliminate from U.S. patent law the ability for an inventor to rely on a *date of invention* to establish whether or not an invention was novel (and thus patentable) over "prior art."

The NRC urged that the United States return to a patent law principle found in the 1793 Patent Act.[7] Under the 1793 Patent Act, only the *filing date of a patent application* was relevant to assessing that an invention was not already "known or used," such that the invention could be considered "novel" and a valid patent could be secured on the inventor's application for patent.[8] The NRC recommended returning to this

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https://www.uspto.gov/sites/default/files/aia_implementation/armitage_pdf.pdf.

[5] National Research Council. 2004. *A Patent System for the 21st Century*. Washington, DC: The National Academies Press. https://doi.org/10.17226/10976.

[6] Patent Act of 1836, 5 Stat. 117.

[7] Patent Act of 1793, 1 Stat. 318.

[8] In 1793, the Congress limited the availability of patents to subject matter "*not known or used before the application*" for patent.

principle such that the *date of invention* would have no continuing relevance in determining patentability.

A corollary to the adoption of this principle arises in the circumstance where different inventors assert that they each independently made the same discovery. In such a circumstance, because invention dates would be disregarded, the *first inventor to file* for a patent, even if not the *first inventor to make the invention*, would alone have the right to patent the invention.[9]

In effect, the NRC recommended that the United States abandon what is commonly referred to as the *first-to-invent* principle for determining patentability (and the inventor's right to a patent otherwise) and adopt instead a *first-inventor-to-file* principle. Doing so is one of the seminal changes to U.S. patent law Congress accomplished through the America Invents Act.[10]

Id., § 1.

[9] See NRC Report, *supra*, at p. 124, "The United States should conform its law to that of every other country and accept the first-inventor-to-file system."

[10] America Invents Act, § 3. See § 3(o), reporting the sense of Congress that "converting the United States patent system from 'first to invent' to a system of 'first inventor to file' will promote the progress of science and the useful arts by securing for limited times to inventors the exclusive rights to their discoveries and provide inventors with greater certainty regarding the scope of protection provided by the grant of exclusive rights to their discoveries."

B. Congress Internationalized Patentability Law, Including By Adopting The First-Inventor-To-File Principle, In Order To Simplify § 102 And Limit It To Novelty And Prior Art Provisions.

At the time the America Invents Act was enacted in 2011, the first-inventor-to-file principle was observed by *every country in the world* except the United States.[11] In addition, in every other country of the world, "prior art" was determined by a pair of straightforward considerations.

In the first-inventor-to-file patent systems outside the United States, prior art consists of essentially two elements: (1) subject matter *publicly disclosed* before the inventor's patent filing and (2) *disclosures made in earlier domestic patent filings*, but only if such earlier patent filings eventually become public (*i.e.*, either when such other applications for patent publish or issue as patents).[12] Congress enacted the first-inventor-to-file principle through the America Invents

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[11] See America Invents Act, § 3(p), reporting the sense of Congress that "converting the United States patent system from 'first to invent' to a system of 'first inventor to file' will improve the United States patent system and promote harmonization of the United States patent system with the patent systems commonly used in nearly all other countries throughout the world with whom the United States conducts trade and thereby promote greater international uniformity and certainty in the procedures used for securing the exclusive rights of inventors to their discoveries."

[12] In the 38 countries adhering to the European Patent Convention, "prior art" used for assessing novelty can arise from only two sources: (1) "everything made available to the public by means of a written or oral description, by use, or in any other

Act in part because of the opportunity it presented to incorporate into U.S. patent law some of the relative simplicity typically present in foreign patent systems.

To maximize the prospects for delivering on this objective, Congress needed to make a fresh start with the patent statute, repealing the statute's core provisions addressing patentability, 35 U.S.C. §§ 102-103. These sections had been respectively titled "*Conditions for patentability; novelty and loss of right to patent*" and "*Conditions for patentability; non-obvious subject matter.*" Congress enacted entirely new §§ 102-103 to replace them.

New § 102 now bears the truncated title "*Conditions for patentability; novelty.*" The comparison of this truncated title to the title of the repealed statute indicates that Congress had repealed, and not replaced, each of the "loss of right to patent" provisions that had formerly been part of § 102.

By jettisoning the "loss of right to patent" from new § 102, the remaining patentability law under new § 102 is now confined—as its truncated title indicates—solely to the question of *novelty* in light of the *prior art*. This title-to-title comparison alone dictates that the courts should reject any construction of the new statute that would carry over any "loss of right to patent" provision from the § 102 repealed to the new § 102.[13]

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way" and (2) "the content of European patent applications as filed." Convention on the Grant of European Patents (Oct. 5, 1973), Article 54.

[13] Congress enacted these new titles into law under the America Invents Act and they represent "positive law titles [that] constitute legal evidence of the law." 1 U.S.C. § 204.

The repealed § 102 from the 1952 Patent Act had contained seven separate subsections providing a collection of individual "prior art" and "loss of right to patent" provisions. With the repeal of the "loss of right to patent" provisions and the ability to simplify the law on "prior art" under the first-inventor-to-file principle, the America Invents Act was able to distill new § 102's conditions for patentability into a single subsection that set out all the subject matter that could now qualify as "prior art" and bar a patent for lack of novelty. This subsection is new § 102(a).

New § 102(a) is titled simply, "*Novelty; prior art,*" indicating that any subject matter that could qualify as "prior art" is now to be found in this single new subsection of the patent statute. Such § 102(a) "prior art" now represents the exclusive basis on which new § 102 imposes a "condition for patentability."

This reference to "prior art" in new § 102(a)'s title is significant for another reason. The appearance of the term "prior art" in § 102(a)'s title and elsewhere in new § 102 was the first time that the term "prior art" had appeared in § 102 itself. Prior to the America Invents Act, the only patentability-related section of the patent statute in which the term "prior art" had appeared was in § 103.[14]

The references to "prior art" in new § 102 were part of an effort by Congress to more clearly tie together new §§ 102 and 103 and to better align and

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[14] Under the 1952 Patent Act, it was merely implicit in the patent statute that the constituents of "prior art" in § 103 addressing non-obviousness were to be found in the prior-art relevant subsections of § 102, and not elsewhere in the statute. See *In re Bergstrom*, 427 F.2d 1394, 1401 (CCPA 1970), confining prior art for novelty purposes to § 102's patent-barring provisions.

more clearly link—and ultimately simplify—the "conditions for patentability" set out under these sections. Indeed, to fully understand and interpret new § 102's provisions, it is essential to understand the ties Congress constructed between these two new sections.

In this regard, repealed § 103 had provided an obviousness bar to patenting that applied "though the invention is not *identically disclosed or described* as set forth in section 102, if the differences between the subject matter sought to be patented and the *prior art* are such that the subject matter as a whole would have been obvious *at the time the invention was made.*"[15] The America Invents Act enacted a new § 103 that instead barred a patent for a *claimed invention* "notwithstanding that the *claimed invention* is not *identically disclosed* as set forth in section 102, if the differences between the *claimed invention* and the *prior art* are such that the *claimed invention* as a whole would have been obvious *before the effective filing date of the claimed invention.*"[16]

Comparing the italicized before-and-after text above, Congress made four significant changes that operate to clarify and unify the relationship between new § 102 and new § 103:

First, Congress made the word "disclosed" in new § 103 the generic term for indicating when an activity can result in the creation of "prior art" under new § 102(a)—or bear on obviousness under new § 103. While repealed § 103 used the alternative "disclosed or described" to reference when § 102 would operate to bar an invention for lack of novelty, under the

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[15] 35 U.S.C. § 103 [1952 Patent Act].

[16] 35 U.S.C. § 103 [America Invents Act].

America Invents Act, it is a *disclosure* that is necessary to create "prior art." Picking up on this simplified terminology, new § 102 now uses the words "disclosed" or "disclosure" no less than 18 times, while repealed § 102 did not make even a single use of either word.

Second, consistent with the first-inventor-to-file principle, new § 103 no longer permits the inventor to resort to a *date of invention* to assess non-obviousness. That assessment is now made with reference to the date of the inventor's patent filing. Because of the importance of patent filing dates, new § 103 utilizes the term "effective filing date," which is a term that the America Invents Act added as a new definition now found in new 35 U.S.C. § 100(i) . This same terminology is now used extensively in new § 102—in a total of six places.

Third, new § 103 adopts a second new definition, enacted as part of the America Invents Act, to provide greater precision in interpreting the new statute. This new definition appears in 35 U.S.C. § 100(j) and defines the term "claimed invention." As used in both new § 102 and § 103, a "claimed invention" refers to "the subject matter defined by a claim in a patent or an application for a patent." The term "claimed invention" now appears a total of 16 times in new § 102.

Fourth, although the term "prior art" from repealed § 103 appears again in new § 103, the context in which the term appears in the new law is different, *i.e.*, the term appears in the context of a first-inventor-to-file statute in which "prior art" is now referenced explicitly in new § 102(a). Given this new context, the same word from the repealed statute now has a quite different meaning, consistent with the first-inventor-

to-file statute in which the "loss of right to patent" provisions of the repealed law have not been reenacted.

As for the "prior art" provisions themselves, under new § 102(a) of the America Invents Act, the types of *disclosures* that now can bar patent claims are set out in two new paragraphs. First, § 102(a)(1), addresses *publicly disclosed* subject matter as prior art. Second, § 102(a)(2), establishes when disclosures from *U.S. patent filings of other inventors* can constitute prior art.

Parsing new § 102(a)(1), this paragraph operates to novelty-bar a patent claim based on "prior art" from any of three categories: if "the *claimed invention* was [1] patented, [2] described in a printed publication, or [3] in public use, on sale, or otherwise available to the public *before the effective filing date of the claimed invention*."

The third of these three categories can be restated more fully by incorporating the definition from new § 100(j). As so restated, new § 102(a)(1) can impose a novelty bar to patenting when the *subject matter defined by the claim* has been in public use, on sale, or *otherwise available to the public*.

C. Congress Replaced "Known," A Word Used To Define Prior Art In Patent Acts Since 1790, With "Available To The Public" To Provide A More Apt and Internationalized "Prior Art" Standard.

The phrase "known or used," up until the America

Invents Act was enacted in 2011, had been used to define prior art in every U.S. patent statute since 1790.[17] In contrast, the phrase "available to the public," now found in § 102(a)(1), had never before appeared in the provisions of the U.S. patent statute setting out "conditions for patentability."

That said, the term "available to the public" had been judicially recognized at the Federal Circuit as a synonym for the term "known," as used in repealed § 102(a) in the phrase "known or used."[18] Further, "available to the public" is a recognized term of art used in patent laws outside the United States to characterize subject matter that can qualify as "prior

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[17] In 1790, Congress provided patents could be granted to inventors for inventions "*not before known or used.*" § 1, Patent Act of 1790, 1 Stat. 109. As noted above, in 1793, the Congress further limited the availability of patents to inventions "*not known or used before the application*" for patent. § 1, Patent Act of 1793, *supra*. In 1836, Congress permitted an inventor to patent only subject matter "*not known or used by others before his ... discovery or invention thereof, and not, at the time of his application for a patent, in public use or on sale, with his consent or allowance, as the inventor or discoverer.*" § 6, Patent Act of 1836, *supra*. In 1870, Congress limited enforceable patent rights to subject matter "*not known or used by others in this country, and not patented, or described in any printed publication in this or any foreign country, before his invention or discovery thereof, and not in public use or on sale [in this country] for more than two years prior to his application.*" §§ 24, 61, Patent Act of 1870, 16 Stat. 198.

[18] "Section 102(a) establishes that a person cannot patent what was already known to others. ... Accordingly, in order to invalidate a patent based on prior knowledge or use, that knowledge or use must have been available to the public." *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).

art."[19]

Outside the United States, the term "available to the public" has long been interpreted to preclude subject matter that remains confidential or otherwise secret from constituting prior art and being used to invalidate a patent. Based on its use outside the United States—as well as its meaning as interpreted by the courts in the United States—it is an alternative (and fully descriptive) way of requiring that subject matter must be *publicly disclosed* to constitute prior art.

By 2011, Congress determined that the time had come to reformulate the statutory text to address the ongoing inaptness—or at least incompleteness—of this phrase "known or used" in setting out the actual limitation on subject matter qualifying as prior art.[20] At the same time, in rewriting § 102 in 2011, Congress was faced with the challenge of reducing the redundancy in two of § 102's subsections (repealed §§ 102(a) and 102(b)) that separately provided that subject matter "patented" or "described in a printed publication" could constitute prior art.

These partially overlapping subsections used different terminology to reference the categories of subject matter other than that arising from patents and printed publications that could constitute prior art.

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[19] European Patent Convention, *supra*, Article 54.

[20] By the time of the 1952 Patent Act, the continued use of the phrase "known or used" was being questioned by Congress given its generality. See H.R. REP. NO. 82-1923 (Appendix, Revision Notes) at p. 17, *i.e.*, "The interpretation by the courts of paragraph (a) [of old § 102] as being more restricted than the actual language would suggest (for example, 'known' has been held to mean 'publicly known') is recognized but no change in the language is made at this time."

Repealed § 102(a) used the phrase "known or used by others in this country," while repealed § 102(b) characterized such subject matter as being "in public use or on sale in this country."

Congress, in crafting new § 102(a)(1), took the approach of effectively concatenating these two subsections and replacing "known" with the more apt and more internationalized term "available to the public"—positioning the latter phrase as a terminal qualifier to limit the preceding categories of § 102(a)(1) prior art to subject matter *publicly disclosed*. Thus, this new qualifier—"or otherwise available to the public"—can be understood to define prior art under new § 102(a)(1) as being limited to the types of *publicly known* subject matter that could have qualified as prior art under repealed § 102(a).

As so limited, this new statute—like repealed § 102(a) before it—vindicates the constitutional function of the patent system to promote progress in useful arts. What is already "known" to the public needs no patent monopoly to encourage its disclosure, but the prospect of exclusive rights under a patent provides a continuing incentive to disclose what the inventor yet holds in confidence and yet remains secret, *i.e.*, has not yet been *publicly disclosed*.

Thus, it follows from the text of new § 102(a)(1) that both "public use" and "on sale" activities, whether or not such activities are attributable to the inventor, can novelty-bar a patent claim, but only *if the actual subject matter defined by the patent claim at issue did not remain confidential or otherwise secret, i.e.*, had become available to the public.

D. Congress's Adoption Of The First-Inventor-To-File Principle Permitted Elimination Of All § 102 "Loss Of Right To Patent" Provisions.

The decision to draft a new patent statute that was devoid of "loss of right to patent" provisions, long part of the patent law, was taken just as seriously by Congress as the companion decision taken in the America Invents Act to abandon a first-to-invent system that had been codified as part of the patent statute since 1836. It was a decision, however, that was made with a compelling justification.

In general, "loss of right to patent" provisions address *inventor-attributable* activities that can result in a particular inventor forfeiting the right to patent—even if the claims to the invention would otherwise have met the patentability requirements as new and non-obvious over the prior art. Such provisions were found in repealed 35 U.S.C. § 102(c), § 102(d), and § 102(f) and in the "in public use" and "on sale" provisions of repealed § 102(b).[21]

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[21] The repealed subsections of § 102 were those related to an inventor's abandonment" of the invention under repealed 35 U.S.C. § 102(c); premature foreign patenting by the inventor or its assignee under repealed 35 U.S.C. § 102(d); and a obviousness-type bar to patenting based on the inventor's private knowledge obtained from others (*OddzOn Products, Inc. v. Just Toys, Inc.*, 122 F.3d 1396 (Fed. Cir. 1997)) under repealed 35 U.S.C. § 102(f). As the courts had interpreted repealed § 102(b), it contained a further "loss of right to patent" provision under which an inventor forfeits the right to patent an invention based upon inventor-attributable activities placing an invention "in public use or on sale." This "loss of right to patent" bar was absolute since it can apply, irrespective of whether the subject

While such forfeitures might be justified policy-wise to preclude an excessive delay in the inventor seeking a patent once an invention had been fully commercialized, this policy justification has limited, if any, importance where the first-inventor-to-file principle applies.

In the first-inventor-to-file world, inventors have an imperative to promptly seek patents on inventions, once made, given the inability to use the date of invention to rescue patentability if the invention in question has been the subject of a pre-filing public disclosure. For this reason, Congress found little justification—whether for policy reasons or otherwise—for reenacting "loss of right to patent" provisions under the America Invents Act.

Moreover, maintaining such provisions, even if a cogent policy justification could have been articulated, would have detracted from congressional efforts to internationalize U.S. patent law by embracing the first-inventor-to-file principle. This would be particularly true of a forfeiture of the right to patent based upon inventor-attributable "on sale" or "public use" activities in which the subject matter defined by the patent claims was not made available to the public. *Maintaining a forfeiture of this type could have left the United States alone in the entire world with such a provision in its patent law.*

Also, given the focus on inventor-attributable activities, including activities of the inventor's assignee,

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matter defined by the patent claims had ever been made, much less been made available to the public. *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998).

such "loss of right to patent" provisions invite discovery of the activities of inventors and their assignees to determine if the patent right has been forfeited. Such provisions in the patent law can greatly compromise the efficiency and effectiveness of yet another seminal change to the U.S. patent law, the new post-grant review procedures enacted as part of the America Invents Act. Congress provided the opportunity for any member of the public to challenge the validity of any newly issued U.S. patent on any ground that could be raised as a defense to the infringement of the patent, but in a proceeding designed with a one-year time limit for reaching a final decision—*a limit premised on Congress's determination that discovery burdens in the old law would be gone in the new.*[22]

Thus, not only did new § 102(a)(1) restrict any bar to patenting to activities producing a public disclosure of the subject matter defined by the claim of a patent—*through the overarching requirement for such subject matter to be made "publicly known" or "available to the public"*—but did so for compelling reasons, *i.e.*, in light of the overall context in which the America Invents Act was conceived and enacted.

E. Any Contention That New § 102(a)(1) Reenacted A "Loss Of Right To Patent" Provision Is Non-Textual.

It is beyond any dispute that the new patent statute under the America Invents Act included no "loss

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[22] America Invents Act, *supra*, § 6(d), adding Chapter 32 to title 35, United States Code providing for the "post-grant review" of patents that are subject to the first-inventor-to-file provisions of the America Invents Act.

of right to patent" provisions corresponding to repealed § 102(c), § 102(d), or § 102(f). However, Congress did reuse terminology found in repealed § 102(b) in new § 102(a)(1). Thus, the only possible textual basis for contending that any "loss of right to patent" provision might somehow remain in a new statutory provision—now titled only "Conditions for patentability; novelty"—lies in the use in new § 102(a)(1) of the carryover terms "in public use" and "on sale" as found in repealed § 102(b).

Under the old patent law, at least as interpreted by the courts, an inventor could suffer the "loss of right to patent" or forfeit the right to secure a patent claim under repealed § 102(b). Such a forfeiture could take place *irrespective of whether the subject matter defined by the claims was made available to the public* based upon "public use" or "on sale" activities that were (1) attributable to the inventor, (2) undertaken in the United States, and (3) took place more than one year before the inventor's U.S. patent filing.[23] This type of forfeiture bar did not apply where the activities in question could not be attributed to the inventor. In such a situation, the subject matter defined by the patent claims needed to be available to the public for a patent to be barred for lack of novelty over the prior art.[24]

The legislative history that accompanied the 1952 Patent Act explained that its § 102(b) was simply restating the law from the patent statute that had come

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[23] 35 U.S.C. § 102(b) [1952 Patent Act], as interpreted in *Pfaff*, *supra*.

[24] *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540 (Fed.Cir.1983).

before it—which the courts had long held to contain such a "loss of right to patent" bar.[25]

Assuming, however, that such a forfeiture-type provision based on inventor-attributable "public use" and "on sale" activities had *not* been part of the U.S. patent law before the America Invents Act was enacted, it is self-evident that the carryover language from repealed § 102(b) could not have itself created such a "loss of right to patent." As written, the "novelty" bar in new § 102(a)(1) cannot be read to mean that "public use" or "on sale" activities attributable to the inventor could result in the forfeiture of the inventor's right to patent—*irrespective of whether the subject matter defined by the claim was available to the public*. A plain reading of the text of the new statute reveals that it does not set out one rule for inventor-attributable "public use" or "on sale" activities and a potentially contradictory standard that would apply to such activities otherwise. Thus, any contention that a "loss of right to patent provision was reenacted in § 102(a)(1) is, at best, non-textual.

Any further contention that such a non-textual forfeiture provision nonetheless must somehow exist within the text of new § 102(a)(1) becomes no less frivolous given the legislative context in which § 102(a)(1) was enacted. Beyond question, the new patent law under the Act was intended to simplify and internationalize our patent law; it was designed to build more transparency into patentability determinations so

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[25] This legislative history provided that for both repealed § 102(a) and § 102(b) of the 1952 Patent Act, "[n]o change is made in these paragraphs [from the prior law] other than due to division into lettered paragraphs." H.R. REP. NO. 82-1923 (Appendix, Revision Notes), p. 17.

that, as in foreign patent systems, patent validity would not turn on secret information, not available to the public—accessible only through discovery and possibly only at the time a patent's validity might be litigated; and the Act expressly repealed the "loss of right to patent" provisions that had existed under the former law and did not reenact any of them. All this context reaffirms that the text of the new patent statute must mean what it plainly indicates—Congress had retired this "forfeiture" element of the patent law in enacting the American Invents Act—new § 102 is now devoid of "loss of right to patent" provisions.

Also, simply because the words "on sale" appear in both repealed § 102(b) and new § 102(a)(1) does not indicate that bars to patenting remain identical under those two provisions—and somehow provide the otherwise missing textual support. Given the quite different context in which the words "on sale" are used in the 1952 Patent Act and the America Invents Act, the contention that all the patent law associated with these words was unchanged is no more tenable than would be the contention that all the law associated with the words "prior art" is unchanged with the repeal of all the provisions in the patent statute setting out the conditions for patentability and their replacement with remarkably different ones.

Most importantly, however, *patent policy matters*. Congress acted, through the America Invents Act, to fulfill the constitutional imperative that the patent system must promote progress in useful arts. To promote progress, a patent law must encourage disclosure of inventions—including disclosures through the patenting process itself—so that such publicly dis-

closed inventions can serve as feedstock for other inventors to make further advances in technology.

Patent forfeiture provisions—including those relating to "on sale" activities in effect under the old patent law—have the effect of encouraging perpetual secrecy for an invention once the possibility for securing a patent has been lost. *Repealing such forfeiture laws can have the opposite effect.* The absence of a forfeiture bar encourages public disclosure through use of the patent system by providing an inventor a *continuing opportunity* to secure a patent on the subject matter that is both novel and non-obvious.

The simultaneous repeal of "loss of right to patent" provisions and the introduction of the first-inventor-to-file principle under the America Invents Act represented measures that work in tandem to effect constitutionally consistent patent policy. The first-inventor-to-file principle *encourages early disclosure* of inventions, once ready for patenting, through prompt patent filings. At that point, the absence of a forfeiture law preserves a *continuing incentive to disclose* novel and non-obvious subject matter through use of the patent system. Thus, neither patent policy nor the constitutional purpose of the patent system assist in the effort to contort the text of the new statute to find textual support for an inventor-forfeiture provision that is otherwise absent.

F. Congress Left No Tenable Ground On Which To Hold That More Than A Novelty Bar Remains in New § 102(a)(1).

What would this Court need to conclude to find that Congress had left the patent statute sufficiently unchanged that it now contains provision under which

inventor-attributable "on sale" activities could bar a patent irrespective of whether the subject matter defined by the patent claims had become available to the public?

Based on an analysis of the new statute above, the Court would need to make one of two untenable determinations in order to affirm the Federal Circuit's holding—

(1) the Court would need to find that Congress enacted in new § 102(a)(1) a "novelty" provision specific to inventor-attributable activities, but one that cannot be grounded on any possible reading of the actual text of a newly enacted statute—*given that § 102(a)(1) was enacted with an overarching requirement for public availability of subject matter that could constitute "prior art" and defeat "novelty."* or

(2) in the absence of finding any supportive statutory text, the Court would need to determine that the provisions of a repealed statute nonetheless carry over into a new statute simply because the same words "in public use" and "on sale" are found in both statutes—*even though doing so (1) would be entirely at odds with the context in which these words appear in the new statute; (2) refute good patent policy; (3) frustrate a historic legislative endeavor to simplify and internationalize our patent law; and (4) negate, rather than advance, congressional efforts to enact more transparent and less discovery-intensive patentability standards.*

In sum, there is no tenable ground on which this Court could take Congress's historic simplification and internationalization of the conditions for patentability in new § 102(a) and—as the Federal Circuit

did—claw the new law back to the old law that Congress had repealed.

II. Under The America Invents Act, "On Sale" Activities Must Make The Subject Matter Defined By A Claim Available To The Public In Order For § 102(a)(1) To Bar A Patent On The Claim.

This appeal deals specifically with "on sale" activities that are attributable to the inventor because they were undertaken by the inventor's assignee, the patent owner Helsinn. However, the new statute self-evidently treats all "on sale" activities the same, whether they are inventor-attributable activities or not. The statute cannot be applied as written if it is given one construction for "on sale" activities that are inventor-attributable and a potentially contradictory construction for activities that are not.

The new statute contains a terminal qualifier on subject matter that can qualify as prior art that cannot be simply disregarded. It states that: "the subject matter defined by a claim" (which is the new statutory definition for the term "claimed invention" in new § 100(j)) must be "on sale, or otherwise available to the public" for new § 102(a)(1) to bar a patent. As written, this language on its face precludes knowledge not available to the public from barring a patent.

As drafted in 1952, now-repealed § 102(b), which expressly provided that a patent could be barred based on "on sale" activities, served as a dual-purpose statute, at least as interpreted by the courts. As interpreted, it imposed both a "prior art" bar (applying

no matter to whom the "on sale" activities were attributable) and a "loss of right to patent" bar (specific to inventor-attributable activities).

The judicial interpretation of the 1952 statute as containing such a dual bar was not expressly precluded in the repealed statute given the open-ended, non-limiting language used in the text of the repealed law. In general terms, repealed § 102(b) simply required the "invention" (not the "claimed invention" defined as "the subject matter defined by a claim") to be "on sale" (but only if so in the United States) outside the one-year period. In addition, there was no overall qualifier on public availability, *i.e.*, the repealed statute did not specifically limit "on sale" activities where the subject matter defined by a claim was available to the public.[20]

Thus, as drafted and unlike the new § 102(a)(1), repealed § 102(b) could presumably accommodate both a "prior art" construction and an inventor-forfeiture function. And, of course, the 1952 legislative history explained that it did just that—since the 1952 Patent Act did not purport to be modifying the patent law with respect to the statutory conditions for patentability from the patent statute that had come before it.

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[20] Had Congress sought to reenact the former "loss of right to patent" bar based "on sale" activities, it most certainly would have reimposed the limitation to domestic activities—and could have readily done so by further qualifying new § 102(a)(1) so that a claimed invention that was in public use or on sale *in this country* as a result of activities attributable to the inventor or a joint inventor of the claimed invention would not be subject to the limitation on availability to the public. During the entire legislative process, no such qualification was ever considered.

According to the facts before the Federal Circuit, all that was *publicly disclosed* from the inventor-attributable "on sale" activities was that the patent owner had agreed "to supply ... 0.25 mg ... palonosetron products." However, the subject matter defined by the claims of the patent detailed a very specific formulation of that product to which the patent claims were limited (*i.e.*, "palonosetron hydrochloride in an amount of 0.25 mg based on the weight of its free base; from 0.005 mg/mL to 1.0 mg/mL EDTA; and from 10 mg/mL to about 80 mg/mL mannitol").

Had the "on sale" activities undertaken here *not* been attributable to the inventor, there could be no § 102 patent bar based upon such activities—either before or after the America Invents Act. The sole effect of the America Invents Act on this appeal must be, therefore, to apply this outcome in the case of non-inventor-attributable "on sale" activities equally to inventor-attributable "on sale" activities.

III. New § 102(b)(1)(B) Confirms The Sole Bar To Patenting Under § 102(a)(1) Arises From *Publicly Disclosed* Subject Matter.

In drafting new 35 U.S.C. § 102(b)(1)(B), Congress excluded as prior art *subject matter disclosed by someone other than the inventor*, otherwise constituting prior art under § 102(a)(1) to an inventor's patent, if the "subject matter disclosed had, before such disclosure, been *publicly disclosed* by the inventor."

For § 102(b)(1)(B) to operate properly, Congress needed to restrict this special exclusion from prior art to the circumstance where the disclosure by the inventor had triggered the start of the one-year "grace

period" set out in § 102(b)(1)(A).[27] This "grace period" is triggered only if the inventor has made a disclosure that would otherwise qualify as prior art under § 102(a)(1). The drafting challenge, therefore, was to *identify text to include in § 102(b)(1)(B) that would be co-extensive with § 102(a)(1)-type disclosures by the inventor.*

The term "disclosed," standing along, would not work for this purpose. This term is used in the new statute as a generic term that covers disclosures that could become prior art under both § 102(a)(1) and § 102(a)(2)—and, a patent-filing disclosure of the type described in § 102(a)(2) does not trigger the start of the "grace period."[28]

Congress solved this drafting challenge using the words *publicly disclosed*. Because Congress had limited § 102(a)(1) prior art to subject matter publicly disclosed, the use of the term *publicly disclosed* in § 102(b)(1)(B) removed the possibility that its prior art exclusion would apply, for example, to the situation where the inventor had made a non-public disclosure in a provisional patent application[29] that later

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[27] "A disclosure made 1 year or less before the effective filing date of a claimed invention shall not be prior art to the claimed invention under [§ 102](a)(1) if ... the disclosure was made by the inventor...." 35 U.S.C. § 102(b)(1)(A).

[28] The generic nature of the term "disclosed" in the new statute is most clear from new § 103 that now uses the phrase "disclosed as set forth in section 102" to reference subject matter disclosed under both § 102(a)(1) and § 102(a)(2).

[29] Under 35 U.S.C. § 111(b), provisional patent applications cannot issue as patents and never become public unless converted to a nonprovisional application or used as a basis for claiming priority under 35 U.S.C. § 119(e).

was abandoned and had never become public. Thus, *publicly disclosed* is the perfect synonym for *disclosed under § 102(a)(1)*.

If this *public* disclosure limitation had not been placed into the statute, an inventor could have filed and abandoned a provisional application *years before* someone else had independently discovered and published in the same subject matter. Without the word "publicly," the inventor could assert entitlement to exclude the later publication by someone else as prior art under § 102(b)(1)(B)—even if the prior art disclosure had appeared years after the inventor abandoned the provisional patent filing.

Congress avoided creating such a loophole in the new statute through the *publicly disclosed* limitation. By requiring the inventor to publicly disclose, thereby creating § 102(a)(1) prior art, and thereby triggering the start of the one-year "grace period," the inventor would be forced to seek a patent during the one-year period or forfeit the right to patent on the *publicly disclosed* subject matter altogether.

The text of § 102(b)(1)(B), thus, confirms that the patent statute now uses the term "publicly disclosed" interchangeably with the concept of "disclosed as set out in § 102(a)(1)." They can be regarded as perfect synonyms. Thus, to the extent the text of new § 102(a)(1) was not completely unambiguous that § 102(a)(1) was limited to *publicly disclosed* subject matter that could bar a patent, the choice of the term "publicly disclosed" in new § 102(b)(1)(B), as a synonym for what can bar a patent under § 102(a)(1), erases any possible ambiguity.

IV. The Mere Repetition Of The Words "On Sale" From The Repealed Statute Provides No Basis For Concluding The Law In The New Statute Remains Unchanged

The Federal Circuit opinion below appears to have considered the presence of the words "on sale" in the new statute as almost by itself a sufficient justification for referencing all the old "on sale" precedents and invoking all the old patent policy that had applied under the 1952 Patent Act. This is not a sufficient basis for overriding the new statutory context in which words from a repealed statute might be reused.

Like the words "on sale," the term "prior art" is reused in the America Invents Act from the 1952 Patent Act. The term "prior art" appears in repealed § 103 to reference a collection of activities that take place *before the inventor's date of invention*. Under the America Invents Act, a new § 103 uses this identical term in the new context of a first-inventor-to-file system. As part of that new context, the America Invents Act removed all references to the date of invention from the patent statute and did not reenact any of the provisions found in the 1952 Patent Act dealing with prior inventions of others being prior art.[30]

In this context, the reuse of the term "prior art" cannot sensibly be understood to mean that all the holdings in which the term was construed under the 1952 Patent Act have survived. The survival of meanings relating to the date of invention, for example, would be inconsistent with the first-inventor-to-file context of the use of the term in the new statute.

Finding that "on sale" carries with it every old

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[30] 35 U.S.C. § 102(g).

meaning, including the patent law that applied based upon the forfeiture or "loss of right to patent" arising from inventor-attributable activities that apply irrespective of whether the subject matter defined by a claim is available to the public, similarly makes no sense in the context of a new patent statute under which no reference to such "loss of right to patent" provisions is anywhere to be found. Like the term "prior art," the term "on sale" must be construed in its new statutory context—where there is no basis to conclude the repetition of these words somehow negated the explicit repeal of the "loss of right to patent" provisions.

V. Whatever Policy Justification May Have Existed For The "On Sale" Bar Applied By The Federal Circuit, It Has Disappeared Under The America Invents Act.

The policy rationale that must undergird the Federal Circuit decision is that at some point an inventor engaging in "on sale" activities must be forced to choose between seeking a patent and forfeiting the right to patent, even if such "on sale" activities are confidential and the invention remains secret. The courts have held that the prior patent laws had reflected such a policy by providing a one-year or two-year period from the start of "on sale" activities that were attributable to the inventor before such a forfeiture of the right to patent would be imposed.[31]

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[31] The patent statutes have historically contained either a one-year or two-year "grace period" during which "in public use" or "on sale" activities attributable to the inventor could be disre-

However, the manner in which such a bar has been implemented by the courts has always had elements that were more punitive than principled. For example, in *Pfaff v. Wells* the "on sale" bar was applied to an invention before it had ever been actually made—when it was merely "ready for patenting"—and applied when the commercialization activities were otherwise inconsequential, *i.e.*, one-off sales that were at most *de minimis*. The result of such an oversized bar has been to impose a burden on the inventor to seek a patent unjustifiably early, if for no other reason than the standard for "readiness" can be so subjective and threshold for triggering the bar can be so low.

For an invention never actually made in physical form nor yet available for purchase—or sold only in trifling quantities or "on sale" only for a matter of days beyond an arbitrary deadline—there is not now nor has there ever been any compelling patent policy that should demand absolute forfeiture of the right to patent. Whatever rule might be justified in the case of substantial, longstanding, and ongoing "on sale" activities (*i.e.*, sales in which profits from commercially significant quantities sold have been realized, with such sales taking place over a period of many years

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garded in determining patentability. By 1897, Congress had restated the primary conditions for patentability to permit an inventor to patent only subject matter "*not known or used by others in this country*, before his invention or discovery thereof, and not *patented or described in any printed publication in this or any foreign country*, before his invention or discovery thereof, or more than two years prior to his application, and not *in public use or on sale in this country for more than two years prior to his application*." Patent Act of 1897, 29 Stat. 692. In 1939, Congress reduced the two-year period to one year. § 1, Patent Act of 1939, 53 Stat. 1212.

before seeking a patent), it is hard to articulate a similar justification for barring a patent—as in this appeal—based upon a supply contract where nothing was ever supplied in domestic commerce before the patent was sought.

In any event, whatever rule might or might not have been justified policy-wise under the 1952 Patent Act requires rethinking under the America Invents Act's first-inventor-to-file principle that inherently encourages prompt patent filing in a manner that the old first-to-invent system did not. Most certainly, Congress would not have acted to expand such a forfeiture bar to encompass confidential "on sale" activities *taking place anywhere in the world*, in part given the fantastically negative implications of doing so as the America Invents Act was simultaneously creating post-grant review procedures required to meet a one-year deadline for adjudicating the potential patent invalidity implications of such activities.

The entire purpose of the patent system is to encourage disclosure over secrecy. Progress in the useful arts is promoted under the patent laws when inventors disclose their inventions so that others might improve upon them. *A patent act fulfilling this primary purpose of the patent laws would provide inventors with a continuing incentive to disclose rather than maintain secrecy.*

The first-inventor-to-file system operates to this end in part because prior art is measured based on the effective filing date of the claimed invention. Waiting a day too long to file for a patent means that new prior art, appearing even a day before the patent filing was accomplished, may render the invention no longer novel or obvious—and no longer patentable.

While a first-inventor-to-file system can be seen as encouraging a race to make an invention available to the public—through the patenting process—the "on sale" bar that the Federal Circuit imposed on this first-inventor-to-file system simply negates the incentive for public disclosure. Once the Federal Circuit's "on sale" bar takes hold for an invention not thereby made available to the public, the inventor has an incentive to continue the "on sale" activities without ever making the invention available to the public. *Continued secrecy becomes the only means for protecting the invention from copying once the right to patent has been forfeited.*

The *coup de grâce* to any notion of carrying the bar forward into the first-inventor-to-file world is its negation of any continuing incentive to disclose an invention as yet unavailable to the public—leaving the inventor with the sole option of continuing secrecy as the best means for securing economic benefit from continuing commercialization. In repealing—and not reenacting—a bar to a patent claim based upon "on sale" activities specifically attributable to the inventor *irrespective of whether the subject matter defined by the claim was available to the public*, Congress was being careful to reflect the policies that ought to govern a patent law calculated to promote progress in useful arts, by exalting a continuing incentive to disclose over encouraging continued secrecy.

CONCLUSION

The America Invents Act cannot—and should not for any sound policy reason—be understood to bar a patent for a claim based upon "on sale" activities attributable to the inventor in which the subject matter defined by the patent claim has not been made available to the public. That is how the statute was written and should be applied.

Respectfully submitted,

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August 23, 2018

No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR SPCM S.A. AND HIGH TECH INVENTORS ALLIANCE AS *AMICI CURIAE* SUPPORTING RESPONDENTS

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October 16, 2018

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INTEREST OF AMICI CURIAE

SPCM S.A. and related companies ("SNF") are leading developers, manufacturers, and marketers of water-soluble polymers (*see* http://www.snf-group.com/).[1] SNF products are used in diverse fields including drinking water production, wastewater treatment, sludge dewatering, oil and gas extraction, mining, agriculture, and the manufacture of paper, textiles, and cosmetic preparations. SPCM S.A. holds dozens of United States patents and pending patent applications.

The High Tech Inventors Alliance ("HTIA") is dedicated to advancing a patent system that promotes and protects real investments in technologies and American jobs.[2] Collectively, HTIA's members employ nearly 500,000 U.S. employees, spent $63 billion last year alone on research and development, and hold more than 115,000 U.S. patents.

As industrial firms selling real products embodying important technologies, SPCM S.A. and HTIA are vitally interested in when a claimed invention is rightly deemed "new" (35 U.S.C. § 101) and thus eligible for patent protection. Petitioner is effectively urging this Court to adopt a radical new concept of "new" that conflicts with the settled understanding of the term.

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[1] No counsel for a party authored this brief in whole or in part and no party or counsel for a party made any monetary contribution intended to fund preparing or submitting this brief.

[2] HTIA is described at https://www.hightechinventors.com/. The eight HTIA members are Adobe, Amazon, Cisco, Dell, Google, Intel, Oracle, and Salesforce.

SUMMARY OF THE ARGUMENT

Section 101 of the Patent Act codifies a simple, intuitive, and longstanding policy of U.S. patent law: Patents are generally available only for "new" technologies. 35 U.S.C. § 101. For more than half a century, the precise details of what constitutes a "new" invention have been codified in § 102 of the Patent Act. 35 U.S.C. § 102. As this Court noted in *Diamond v. Diehr*, 450 U.S. 175 (1981), § 102 is "in effect, an amplification and definition of 'new' in section 101." *Id.* at 191 (quoting S. Rep. No. 82-1979, at 6 (1952)). Consistent with the Patent Act's overarching policy of limiting patents to "new" technologies, this Court has long interpreted the Patent Act's detailed definitions of prior art broadly so that patents may not be granted to technologies that are fundamentally not "new."

Petitioner's argument in this case is that the *addition* of a new residual category of prior art to § 102 in 2011—expanding the prior art to include technologies that are "otherwise available to the public"—worked a wholesale revolution in patent law by *subtracting* substantially from preexisting categories of prior art. Under Petitioner's argument, technologies that have been "on sale" for years or even decades would now suddenly be patent-eligible if sellers of products or processes embodying such old technologies included non-disclosure provisions in private terms of sale.

As detailed in Part I of this brief, Petitioner's argument goes against more than 170 years of this Court's precedents, which have consistently interpreted the Patent Act's prior art categories broadly. It is telling that neither Petitioner nor the Government cites a single precedent of this Court that excluded old technology

from any category of prior art on the basis that the terms of a commercial sale included a non-disclosure provision.

As shown in Part II, the Government has proposed a highly revisionist, vague, and dispute-inviting interpretation of "available to the public" which conflicts both with the most natural meaning of the statutory text when viewed in historical context and with the usage of the phrase by this Court in its applicable precedent. The Government's proposed interpretation of "available to the public" would drastically contract the "on sale" category of prior art and subvert long-established patent law and policy, which restricts patent grants to claimed inventions that are "new." 35 U.S.C. § 101.

As shown in Part III, beside contravening the basic patent policy codified in § 101 of the Patent Act and reflected in precedents of this Court, Petitioner's proposed construction of amended § 102(a)(1) also violates multiple canons of statutory interpretation. To accept Petitioner's argument, this Court would have to believe that Congress:

1. Attempted to change this Court's construction of the "on sale" category of prior art by reenacting that exact statutory phrase;

2. Attempted to change the meaning of that reenacted statutory phrase by adopting a related but not utterly inconsistent provision elsewhere in the statute;

3. Attempted to *subtract* from the reenacted category of prior art by *adding* a new category of prior art;

4. Attempted to rely on the disjunctive word "or" between the phrases "on sale" and "available to the

public" as a means of communicating the conjunctive, so that the reenacted version of "on sale" prior art would be interpreted to mean that the prior art must be *both* "on sale" (under the traditional meaning of that phrase) *and* "available to the public" (under some undefined and restrictive meaning);

5. Attempted to rely on the adverb "otherwise" as a signal that all statutory categories of prior art should be subject to the *same* standard of being "available to the public" even though the word "different" is included in prominent definitions of "otherwise";

6. Attempted to narrow preexisting categories of prior art to the point of rendering them superfluous to the operation of the statute; and

7. Attempted to use the phrase "available to the public" to signal an ahistorical and dramatically restrictive approach to prior art even though this Court's precedents suggest that the phrase should be construed broadly.

Each of these steps violates specific canons of statutory construction, basic common sense, or both. Collectively, they make Petitioner's interpretation of § 102(a)(1) wholly implausible.

Finally, as discussed in Part IV, Petitioner's implausible interpretation of § 102(a)(1) should also be disfavored because it raises a serious constitutional issue concerning the scope of congressional power to grant patents for subject matter that is in the public domain under federal patent law.

Before this Court Petitioner has not disputed that its claimed invention was "on sale," within the meaning

of pre-AIA § 102 and its statutory predecessors, more than one year before the date when it filed its priority patent application (*i.e.*, January 30, 2003). It is, thus, established that at the time Petitioner filed its priority patent application, its claimed invention was no longer "new" (35 U.S.C. § 101) under then-existing patent law. Petitioner contends, however, that by passing the America Invents Act ("AIA") in 2011, Congress purportedly authorized the granting of patents for subject matter that had been in the public domain, in Petitioner's case, for the better part of a decade. Such an interpretation of the AIA would raise a serious constitutional question concerning the scope of congressional power to authorize patents for public domain subject matter. Standard canons of statutory interpretation require rejection of such an interpretation when another reasonable interpretation exists.

I. 35 U.S.C. § 101 AND THIS COURT'S PRECEDENTS LIMIT PATENT-ELIGIBILITY TO "NEW" TECHNOLOGIES.

Since 1793, United States patent statutes have expressly limited patent-eligible subject matter to "new" inventions. Consistent with that explicit statement of an overarching policy in U.S. patent law, this Court's precedents have taken a broad approach to defining the prior art categories that are used in evaluating the novelty of a claimed invention.

Petitioner in this case seeks a radical departure from this consistent tradition. It asks the Court to remove from the "on sale" category of prior art any sale whose terms included a non-disclosure provision that could be argued to make a patented article not "available" to a sufficient number of the right kind of third-

parties who might, collectively, be deemed "the public." Petitioner's argument should be rejected on multiple grounds, but most fundamentally, it should be rejected because Congress has not altered U.S. patent law and policy to authorize the granting of patents for old inventions whose commercial exploitation may have occurred under private contractual terms that included non-disclosure provisions.

A. U.S. Patent Law and Policy Has Long Authorized Patent Grants Only for "New" Claimed Inventions.

Section 101 of the Patent Act establishes an important polestar for interpreting the remainder of the Patent Act: it authorizes the granting of patents only for subject matter that is "new and useful," "subject to the conditions and requirements of this title." 35 U.S.C. § 101. That single sentence provides two important principles that, historically, have guided this Court's decisions applying the novelty condition for patentability and should control the Court's decision in this case.

First and foremost, the word "new" in § 101 indicates the overarching congressional policy of granting patents only for subject matter that can, in some significant and meaningful sense, be described as "new." The limiting of patent grants to "new" subject matter has been present in every United States patent statute enacted for more than two centuries. The 1793 Patent Act, which was quite possibly drafted by Thomas Jefferson himself, began this long tradition by stating in its very first section that patents were available for "any *new and useful* art, machine, manufacture or composition of matter, or *any new and useful* improvement on any art, machine, manufacture or composition

of matter." Act of Feb. 21, 1793, ch. 11, § 1, 1 Stat. 318, 319 (emphasis added). Since then, the phrase "new and useful" has been reenacted each and every time that Congress has made a general revision or recodification of U.S. patent law. *See* Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119; Act of July 8, 1870, ch. 230, § 24, 16 Stat. 198, 201; 35 U.S.C. § 101 (1952).

A second and equally important point is that the statutory sentence in § 101 also makes the availability of patent protection "subject to the conditions and requirements" of the remainder of the Patent Act (title 35). Thus, the text of § 101 expressly ties together the general policy of limiting patents to the "new" with the more detailed "conditions and requirements" found elsewhere in the Patent Act.

With respect to the concept of novelty, for more than sixty years, the statutory definition of when a claimed invention is "new" has been codified in 35 U.S.C. § 102. In *Diehr*, this Court stated that 35 U.S.C. § 102 is "in effect, an amplification and definition of 'new' in section 101." 450 U.S. at 191 (quoting S. Rep. No. 82-1979, at 6 (1952), *as reprinted in* U.S.C.C.A.N. 2394, 2399).

This case involves the interpretation of some of the details of novelty analysis that are codified in § 102, but any interpretation of those details should not undermine the fundamental policy of limiting patent grants to subject matter that is "new." Rather, interpretation of the details should be consonant and harmonious with the fundamental policy that is expressly set forth in § 101. *See United States v. Fisher*, 6 U.S. 358, 405 (1805) (Marshall, J.) (preferring a statutory construction that "renders the law uniform throughout, and consistent with what it professes in every other

section"); *see also Price v. Forrest*, 173 U.S. 410, 427 (1899) (holding that even a statutory "preamble may be referred to in order to assist in ascertaining the intent and meaning of a statute fairly susceptible of different constructions").

1. This Court Has Construed "on Sale" Expansively and as Time-Based.

The particular part of § 102 at issue in this case is the "on sale" category of prior art, which dates back to patent statutes enacted in 1836 and 1839. The 1836 Patent Act provided that patents could not be granted for subject matter that was (i) "known or used by others before" the date of invention, or (ii) "in public use or on sale, with [the inventor's] consent or allowance" at the time of the patent application. Act of July 4, 1836, ch. 357, § 6, 5 Stat. 117, 119.

The 1836 Act thus defined and measured novelty at two different times. At the time of invention, the alleged invention had to be new in the sense that it was "not known or used by others." At the time of patent application (which would generally be later than the time of invention), the alleged invention still had to be new in the sense that it could not be "in public use or on sale" with the inventor's consent.

In 1839, Congress redefined patent-eligibility in two ways. First, a two-year grace period was allowed so that an alleged invention could still be patented where any "purchase, sale, or prior use" was not "more than two years prior to such application for a patent." Act of Mar. 3, 1839, ch. 88, § 7, 5 Stat. 353, 354. Second, the 1839 Act provided that a sale made more than two years prior to a patent's filing date negated novelty ir-

respective of a putative patentee's "consent or allowance" with respect to the sale.

Thus, after the 1839 Act, the "on sale" category had a two-year grace period but applied to sales activity of anyone, not just a putative patentee. As this Court construed the 1839 Act, "[t]he evident purpose of the section was to fix a period of limitation which should be certain, and require only a calculation of time, and should not depend upon the uncertain question of whether the applicant had consented to or allowed the sale or use." *Andrews v. Hovey*, 123 U.S. 267, 274 (1887).

Although the statutory grace period was shortened from two years to one in 1939, *see* Act of Aug. 5, 1939, ch. 450, 53 Stat. 1212, the basic contours of the "on sale" category of prior art have not been substantially changed since this Court's decision in *Andrews*. In *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), the Court held that "on sale" encompasses offering to supply a product whose design is known, even if no physical embodiment of the product exists at the time of the offer. *Id.* at 58–59, 68-69. Petitioner has not disputed that the traditional understanding of "on sale" encompasses the sale transactions which the Court of Appeals held invalidated three pre-AIA patents held by Petitioner.

2. AIA Carried Forward "on Sale" as a Criterion Defining "New" or Novelty.

As amended in 2011, 35 U.S.C. § 102 excludes from patent-eligibility any claimed invention that was, among other things, "in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." The AIA thus expressly

carried forward the "on sale" prior art category in § 102. By statutory definition, a claimed invention ceases to be "new" (35 U.S.C. § 101) no later than one year after it is placed "on sale." 35 U.S.C. § 102(a)(1); *see also* 35 U.S.C. § 102(b)(1) (excluding from consideration some prior art that arises "1 year or less before" a patent application's effective filing date).

Nothing in the phrase "on sale" excludes offers in which a commercial buyer agrees to exploit licensed technology in a certain manner, such as maintaining the confidentiality of technology so as to maximize the patentee's profit from the claimed invention's commercial exploitation. The idea that such a private agreement could impair public rights to practice old technologies is antithetical to this Court's treatment of similar agreements. *Cf. Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 257 (1945) (holding that a contract could not restrict a party's right to make use of an invention that had fallen into the public domain because such a private agreement cannot be used as "the means of successfully avoiding the requirements of legislation enacted for the protection of a public interest").

Against this background of long continuity, Petitioner argues that Congress's addition of a new category of prior art in § 102(a)(1)—art that is "otherwise available to the public"—effected a revolutionary change in the law. According to Petitioner, this new language modifies "on sale" so that it excludes sales whose terms of sale include non-disclosure provisions and does so even where, as in this case, a sale admittedly would have negated novelty under *Pfaff* and other pre-AIA decisions construing the "on sale" category.

There are many problems with Petitioner's argument, including that it requires this Court to find a negative implication in the single word "otherwise" that overturns settled meanings of previously interpreted phrases in the statute. But the overarching point is that, under Petitioner's interpretation, technology embodied in products on sale for decades could be excluded from the prior art to a patent if sellers and licensors merely included non-disclosure provisions in their sale terms. Petitioner's proposed interpretation of § 102 would make the old patentable, in direct contravention of the "new" limit codified in § 101 of the Patent Act, and in a manner dramatically inconsistent with the approach that this Court has long taken in generously construing prior art categories.

B. This Court's Precedents Have Long Interpreted 35 U.S.C. § 102 and Its Predecessor Statutes as Enforcing the Overarching Policy of Limiting Patent Protection to Subject Matter That Is Actually "New."

As noted above, the word "new" has been an express limit on patent-eligibility in every patent statute dating back to 1793. And in a long and unbroken line of decisions dating back to at least 1851, this Court has rigorously enforced the novelty condition for patentability as excluding subject matter that was not substantially "new," either because the claimed invention was old at the time of invention due to another's work or, as in this case, because the claimed invention was too old when the patent application was filed due to the lapse of a statutory period for filing a patent application.

In *Pfaff*, the patent-in-suit disclosed and claimed a computer chip socket comprising several features. The asserted claims encompassed a computer chip socket that the patentee had offered to supply to a single customer more than one year before the patent's priority date. 525 U.S. at 58–59. This Court held the asserted claims invalid "because the invention had been on sale for more than one year in this country before he filed his patent application." *Id.* at 68–69. *Pfaff* is thus a case prescribing when a sale event creates patent-defeating prior art. As in this case, Pfaff's own work entered the public domain one year after his placing the invention "on sale," and thus his invention was not "new" under the specific statutory test in § 102 by the time he sought a patent.

In *Smith v. Hall*, 301 U.S. 216 (1937), the patent-in-suit disclosed and claimed a method for staged incubation of eggs. The asserted claims encompassed a staged egg incubation method that a single individual, one Milo Hastings, had known and used before the patentee's inventive work. The Court held that this one person's prior knowledge and use was sufficient to invalidate the patent. "It is enough," the Court held, "if he [Hastings] knew and used the method with operative success." *Id.* at 226–27. "He [Hastings] knew the method and used it in a device capable of employing it." *Id.* at 233. The claims were invalid as encompassing subject matter that was "known or used by others in this country, before his invention or discovery thereof." *Id.* (quoting 35 U.S.C. § 31 (1934)). The claimed Smith invention was not "new" under the then-existing statutory test of novelty.

In *Corona Cord Tire Co. v. Dovan Chemical Corp.*, 276 U.S. 358 (1928), the patent-in-suit disclosed and claimed a process of treating rubber or similar compounds which comprised use of an accelerator called diphenylguanidine ("D.P.G."). *Id.* at 366–68. The asserted claims encompassed a method that a single individual, one George Kratz, had discovered and successfully performed within his then-firm before the patentee's work. *Id.* at 382–83. This Court reversed a judgment of infringement on the basis that "the first discovery that D.P.G. was a useful accelerator of the vulcanization of rubber was made by George Kratz and not by Weiss." *Id.* at 385. The claimed Weiss invention was not "new" under the then-existing statutory test of novelty.

In *Brush v. Condit*, 132 U.S. 39 (1889), the patent-in-suit disclosed and claimed an improved electric lamp. The asserted claims encompassed a pre-existing lamp that a single individual, one Hayes, had previously made and that a single firm had used in mill operations for a period of months. *Id.* at 44–49. This Court affirmed a judgment holding the asserted claims invalid in view of the prior Hayes lamp. *Id.* at 49–50. The prior use was of a "public, well-known, practical use in ordinary work." *Id.* at 48. It was irrelevant that "the mechanism of the Hayes clutch was concealed from view," for its design was known to the workmen who installed it. *Id.* at 49 (quoting *Hall v. Macneale*, 107 U.S. 90, 97 (1883)). The claimed Brush invention was not "new" under the then-existing statutory test of novelty.

In *Coffin v. Ogden*, 85 U.S. (18 Wall.) 120 (1874), the patent-in-suit disclosed and claimed a reversible

latch mechanism made by one Kirkham. *Id.* at 121–22. The asserted claims encompassed a reversible latch mechanism that a single individual, one Erbe, had previously made and that a single firm had installed and used in an interior door. *Id.* at 121–24. The patentee argued that this prior knowledge was not "available" to him (*id.* at 121) and so should not be patent-defeating, but this Court disagreed, holding: "The prior knowledge and use by a single person is sufficient. The number is immaterial." *Id.* at 124–25. The claimed Kirkham invention was not "new" under the then-existing statutory test of novelty.

In holding that "prior knowledge and use by a single person is sufficient" to establish that a claimed invention was not "new," the *Coffin* decision cited and followed *Bedford v. Hunt*, 3 F. Cas. 37 (C.C.D. Mass. 1817) (No. 1,217) (Story, J.). In *Bedford*, the patentee argued, just as Petitioner does here, that pre-existing knowledge of a claimed invention should not defeat a subsequent claim of invention except where the prior knowledge "has been before *generally* known and in *general* use, among persons engaged in the art or profession." *Id.* at 38 (emphasis added). Justice Story rejected this argument and held, to the contrary, that: "any patent may be defeated by showing, that the thing secured by the patent, had been discovered and put in actual use prior to the discovery of the patentee, *however limited the use or the knowledge of the prior discovery might have been.*" *Id.* (emphasis added). The *Coffin* decision adopted Justice Story's reading of the novelty condition, *see* 85 U.S. (18 Wall.) at 124–25 & n.*, as did this Court's later decision in *Corona Cord*. *See* 276 U.S. at 382–83 (prior knowledge by a single individual

held sufficient to invalidate a patent; *Bedford* cited and followed).

Coffin also quoted with approval the reasoning of *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 498 (1851). *Gayler* held that an earlier discovery, which had been "finally forgotten or abandoned," was not patent-defeating because it was not "accessible to the public" (51 U.S. (10 How.) at 496–97), in the sense that in that situation "there was *no* existing and living knowledge of this improvement, or of its former use, at the time [the patentee] made the discovery." *Id.* at 498 (emphasis added). The jury instruction approved in *Gayler* followed the longstanding rule that a single person's prior knowledge or use of a claimed invention can be patent-defeating. *See id.* (affirming instruction that if pre-existing fireproof safe and its mode of construction was "still in the memory of Conner," the later inventor would not be entitled to a patent). That is, Conner's knowledge *alone* would have been patent-defeating, if it had not been finally forgotten or abandoned *by him*.

Since at least the *Gayler* decision, patent law has deemed a claimed invention "known" or "accessible to the public" if at least one person, other than the inventor, can legally practice the invention and thereby enable the public to benefit from its use. 51 U.S. (10 How.) at 496–97; *see also Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989) (characterizing former 35 U.S.C. §§ 102(a) and (b) (1988) as excluding from patent protection "knowledge that is already available to the public"). Respondent correctly argues that the new statutory language, "otherwise available to the public," is not rightly treated as negating the long-established meaning of "on sale" in this Court's

precedents (Resp. Br. 22–50); but if it were, that language in patent law parlance clearly encompasses knowledge held by a person, such as a manufacturing licensee or wholesale distributor, who is fully authorized to practice a claimed invention and thereby to enable the public to benefit from its use.

C. Petitioner's Position Would Dramatically Undermine the On-Sale Category of Prior Art.

As the foregoing discussion makes clear, the traditional understanding of "available to the public" is fully consistent with this Court's construction of "on sale" in *Pfaff* and supports the same result in this case as the Court of Appeals reached with respect to Petitioner's three pre-AIA patents disclosing and claiming the same alleged invention. "The law of precedent teaches that like cases should generally be treated alike. . . ." *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1623 (2018).

The contrary interpretation of "on sale" urged by Petitioner would drastically undermine the "on sale" category of prior art and enable sophisticated commercial actors to avoid the traditional implications of commercially exploiting technology. This Court should view with great skepticism Petitioner's claim that the AIA, in making technical revisions to accommodate a change in the *time* for determining when a claimed invention must be "new" (i.e., a change to effective filing date from invention date), effected a revolutionary change in the scope of "on sale" prior art. "Congress 'does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one

might say, hide elephants in mouseholes.'" *Epic*, 138 S. Ct. at 1626–27 (quoting *Whitman v. Am. Trucking Assns., Inc.*, 531 U.S. 457, 468 (2001)).

Construing one of § 102(a)(1)'s predecessor statutes, this Court has noted: "The patentee . . . is not allowed to derive any benefit from the sale or the use of his machine, without forfeiting his right, except within two years prior to the time he makes his application." *Consolidated Fruit-Jar Co. v. Wright*, 94 U.S. 92, 94 (1877) (quotation omitted). Here it is undisputed and admitted that Petitioner derived a benefit from the commercial sale of the claimed invention more than one year prior to the asserted patent's priority date. By 2003, the claimed "invention" was no longer "new" for purposes of U.S. patent protection.

II. THE GOVERNMENT'S PROPOSED INTERPRETATION OF "AVAILABLE TO THE PUBLIC" CONFLICTS WITH APPLICABLE PRECEDENTS OF THIS COURT.

Under this Court's precedents, a claimed invention is "accessible to the public" (*Gayler*, 51 U.S. (10 How.) at 497) if at least one person, other than the inventor, can legally practice the invention and thereby enable the public to benefit from its use. *Id.* at 497–98. "The prior knowledge and use by a single person is sufficient. The number is immaterial." *Coffin*, 85 U.S. at 124–25 (citing *Bedford v. Hunt*, 3 F. Cas. 37 (C.C.D. Mass. 1817) (No. 1,217) (Story, J.)). This reasoning enforces the meaning of "new" in 35 U.S.C. § 101 and undergirds the long line of this Court's precedents set forth in Part I.B, *supra*.

This Court has repeatedly noted: "[W]e should not expand patent rights by overruling or modifying our prior cases construing the patent statutes, unless the argument for expansion of privilege is based on more than mere inference from ambiguous statutory language." *Parker v. Flook*, 437 U.S. 584, 596 (1978) (quoting *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972)). The Government's position rests on disregard of this principle.

Without citing *Gayler*, *Coffin*, *Brush*, or any other of this Court's other precedents which address the issue, the Government asserts that "available to the public" in 35 U.S.C. § 102(a)(1) purportedly does not encompass a pharmaceutical formulation that Petitioner fully disclosed and made available, for money, to a United States wholesale distributor which Petitioner exclusively licensed and authorized to sell the claimed invention in the United States. The Court should reject the Government's argument for the reasons given by Respondent (Resp. Br. 53–59) and for the further reason that the Government's proposed interpretation conflicts with the fundamental limit of patent-eligibility to "new" (35 U.S.C. § 101) subject matter.

Under the traditional understanding of "new," the claimed invention of the asserted patent ceased to be new as of one year after Petitioner offered to license or supply it to a commercial distributor. *See Pfaff*, 525 U.S. at 58–59, 68–69. Under the traditional understanding of "new," it is irrelevant whether Petitioner's vendee was an "ultimate customer[]" (U.S. Br. 26), or what motives Petitioner's vendee might or might not have had for paying $11 million to Petitioner (U.S. Br. 29–30). These types of inquiries are extraneous to the

concept of "new" and are equally extraneous to the traditional understanding of "new" as that term is reflected in precedents like *Gayler*, *Coffin*, *Brush*, *Corona*, *Bedford*, and *Smith* described in Part I.B *supra*.

Lacking any grounding in the statutory text or this Court's precedents, the Government's proposed interpretation of "available to the public" would lead to vast uncertainty and an explosion of litigation over the new, ahistorical meaning the Government implicitly attributes to "available to the public." Under the Government's apparent view, technology could be sold or licensed and commercially exploited for decades and still be deemed "new" if the purchasers or licensees were deemed not to be "ultimate customers" (U.S. Br. 26) or perhaps if the purchasers or licensees all agreed not to retransmit their own knowledge to a *sufficient number* of the *right kind* of *additional* persons who might, collectively, be deemed to constitute "the public."

In *Pfaff* itself, the Government repeatedly emphasized the need for a "bright-line rule" and a "simple test" that would provide "clear notice" of when an invention would be deemed on sale. Brief for the United States as Amicus Curiae Supporting Respondent at 21, *Pfaff v. Wells Electronics Inc.*, 525 U.S. 55 (1998) (No. 97-1130), 1998 WL 351052. The *Pfaff* Court responded by promulgating a clear test. Now, however, the Government seeks to replace clarity with confusion, as demonstrated by its own arguments.

Just three pages after it introduces its "ultimate customers" test, the Government argues that the sale in *Pfaff* counted because the purchaser Texas Instruments was "the *ultimate purchaser* of the sockets as discrete units of commerce." U.S. Br. 29. Which is the

right test—"ultimate customers" or "ultimate purchaser"? And in what circumstances should an actual commercial purchaser not be considered the "ultimate" purchaser? The Government has no answers, but the multitudinous possible commercial purchasing relationships will surely provide many opportunities to litigate such uncertainties.

Much commercial software is distributed in binary form and licensed on terms that prohibit reverse engineering. Technology embodied in such licensed software is "available to the public" under *Gayler* and its progeny, but the Government now suggests that such technology may *not* be "available to the public" and may be forever "new" depending on who the licensee is or what the license terms are.

Advanced semiconductor products comprise transistors that are only a few atoms wide such that reverse engineering is not readily possible. When such products are sold, technology embodied in them is "available to the public" under *Gayler* and its progeny, but the Government now suggests that such technology may *not* be "available to the public" and may be forever "new" depending on who the buyer is or what license terms may accompany the sale.

Examples could be multiplied, but by now the point should be clear: the Government is asking the Court to conclude that 35 U.S.C. § 102(a) purportedly hides an elephant—a revolutionary change in the meaning of "new" and the long-established "on sale" category of prior art—in a mousehole, "otherwise available to the public," which as used in this Court's precedents is fully consistent with the traditional meaning of "on sale."

III. THE AIA'S ADDITION OF A NEW CATEGORY OF PRIOR ART DID NOT CONSTRICT THE PRE-EXISTING CATEGORIES OF PRIOR ART.

In seeking certiorari, Petitioner "unconditionally stated" that "this Court may assume that the Federal Circuit correctly determined that the [sales agreements between Petitioner and its licensee and wholesale distributor, MGI] satisfy the pre-AIA on-sale bar; it is the Federal Circuit's core holding about the effect of the AIA that demands this Court's review." Pet. Reply at 3 (quoting Pet. at 33). That concession makes this case easy to understand: Petitioner has conceded that its license and supply agreements placed the claimed invention "on sale" under *Pfaff* and other precedents applying pre-AIA law. The issue in the case then boils down to whether Congress *changed* the meaning of "on sale" when it enacted the AIA. Petitioner's argument that Congress did so violates multiple canons of statutory interpretation.

As discussed above in the summary of argument, Petitioner's statutory argument about the effect of the AIA is implausible for at least seven different reasons. As shown in Part A below, Petitioner's interpretation violates two canons of statutory interpretation associated with *stare decisis* and statutory stability. Part B demonstrates that Petitioner's interpretation is semantically implausible for three distinct reasons. Finally, as discussed in Part C below, Petitioner's interpretation is contextually implausible for two additional reasons.

A. Petitioner's Interpretation of § 102(a)(1) Violates Multiple "Stabilizing Canons" of Statutory Construction.

Petitioner's argument violates at least two of what are sometimes called the "stabilizing canons" of statutory construction: the canon associated with reenacted statutory text and the canon associated with authoritative judicial constructions. *See* Antonin Scalia & Bryan A. Garner, Reading Law 318, 322, 331 (2012).

First, under longstanding precedents of this Court, congressional reenactment of a statutory term or phrase of art that has been authoritatively construed by the courts should be viewed as a ratification of that prior construction. *See id.* at 322 (where a word or phrase has been authoritatively interpreted, reenactment of the word or phrase in a "later version of [the statute] is presumed to carry forward that interpretation"); *Bragdon v. Abbott*, 524 U.S. 624, 645 (1998) (applying canon). In this case, Congress reenacted the "on sale" category of prior art in 2011, years after this Court in *Pfaff* had given a definitive interpretation of that category of art. Such congressional action is wholly inconsistent with an intent to reject this Court's precedent and to restrict that category of prior art.

Second, in *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S. Ct. 1514 (2017), the Court instructed that, when Congress wants to change the settled meaning of a statutory provision, "it ordinarily provides a relatively clear indication of its intent in the text of the amended provision." *Id.* at 1520. Petitioner's main textual argument is that, even though Congress reenacted the phrase "on sale" as a category of prior

art, still Congress intended to change the meaning of the "on sale" category of art because the new statute includes a new additional category—art that is "otherwise available to the public."

That argument must be rejected under *TC Heartland*. Quoting the late Justice Scalia's co-authored work on statutory interpretation, *TC Heartland* endorsed the view that "[a] clear, authoritative judicial holding on the meaning of a particular provision should not be cast in doubt and subjected to challenge whenever a related though not utterly inconsistent provision is adopted in the same statute . . . ." *Id.* at 1520 (quoting Scalia & Garner, *supra*, at 331).

The phrase "on sale" was authoritatively interpreted in *Pfaff* and, as Petitioner does not now dispute, the license and supply agreements between Petitioner and its wholesale distributor, MGI, satisfy the pre-AIA *Pfaff* standard for "on sale" prior art. Under *TC Heartland*, a change elsewhere in the statute—even though it is a change in the very same statute—should not upend *Pfaff* unless the addition of the category of "otherwise available to the public" art is "utterly inconsistent" with *Pfaff*'s interpretation of the "on sale" category of prior art. Petitioner cannot meet that standard because, as explained below, there is a perfectly sensible interpretation of the new statutory language that requires no modification of *Pfaff*'s interpretation of the "on sale" category of prior art.

B. Petitioner's Interpretation Is Semantically Implausible.

Three distinct semantic problems arise from Petitioner's argument that Congress's addition of the lan-

guage "or otherwise available to the public" was intended to narrow the pre-existing categories of prior art.

First, it is wholly unbelievable that Congress decided the best way to demonstrate its supposed intention to *subtract* from the existing scope of prior art categories was to *add* a new category of prior art. Far more believable is that, in adding the new category of prior art, Congress intended to expand the scope of prior art. That view—that words of addition were in fact intended to add—comports with what is the primary semantic canon of statutory construction, which is that words should be given their ordinary meanings. *See* Scalia & Garner, *supra*, at 69 (describing this as "the most fundamental semantic rule of interpretation").

Second, Petitioner's argument requires a belief that Congress relied on the *disjunctive* word "or" between the phrases "on sale" and "available to the public" as a means of communicating the *conjunctive*, so that the reenacted version of "on sale" prior art would be interpreted to mean that the prior art must be both "on sale" (under the traditional meaning of that phrase) and "available to the public" (under some supposedly new and restrictive sense). That argument violates the semantic that the word "or" denotes the disjunctive. *See* Scalia & Garner, *supra*, at 116 (elaborating on the "conjunctive/disjunctive canon"). As this Court stated in *Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979), "[c]anons of construction ordinarily suggest that terms connected by a disjunctive be given separate meanings, unless the context dictates otherwise."

Third, Petitioner's interpretation also requires the word "otherwise" in the phrase "or otherwise available

to the public" to signal that all listed categories of prior art should be subject to the *same* standard even though prominent definitions of "otherwise" denote difference not sameness.

Under Petitioner's position, the word "otherwise" supposedly "makes clear that the preceding clauses describe things that are of the *same* quality or nature as the final clause. Pet. Br. 27 (quoting legislative floor speech) (emphasis added). Yet using the word "otherwise" as a way to signal that all of the categories should be subject to the "same" standard is, to put it mildly, quite strange given that the word "different" is prominent in common definitions of "otherwise." Webster's New Int'l Dictionary (1961) (defining otherwise as meaning "In a different way or manner" or "In different circumstances").

A perfectly reasonable alternative to Petitioner's interpretation is easily found within the ordinary dictionary definitions of "otherwise," which is commonly used to denote "in different circumstances." *Id.* That definition supports Respondent's reading of the statute. Something becomes prior art if it is "in public use, on sale, or [in different circumstances] available to the public." In other words, a work enters the prior if it fits within circumstance 1 (in public use), circumstance 2 (on sale), or in different circumstances, if the work is available to the public. The word "otherwise" then signals to the reader that the final category of art is directed to circumstances not covered in the "in public use" or "on sale" contexts. That is a perfectly logical way to write a sentence, especially where circumstances constituting "in public use" and "on sale" have been well defined by more than a century of legal precedent.

C. Petitioner's Interpretation Is Contextually Implausible.

Petitioner's proposed interpretation of "or otherwise available to the public" is contextually implausible for two distinct reasons. First, it violates the canon against superfluous language. Second, it requires importing to the phrase "available to the public" an ahistorical and dramatically restrictive meaning even though this Court's precedents embrace a broader meaning that encompasses the traditional scope of the "on sale" category of prior art.

Under the contextual canon against creating statutory surplusage, courts have a "duty 'to give effect, if possible, to every clause and word of a statute,'" and if possible, to avoid "emasculat[ing]" portions of the statute. *United States v. Menasche*, 348 U.S. 528, 538–39 (1955) (quoting *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883)); *see also* Scalia & Garner, *supra*, at 174 (listing the "surplusage canon" as one of the important "contextual canons"). Petitioner argues that "Respondents' interpretation would leave 'otherwise' with no function, violating the rule against superfluity." Pet. Br. 37. That is not true because, as explained above, the word "otherwise" is sensibly interpreted to mean "in different circumstances." In fact, it is Petitioner's construction that creates a problem with superfluous language, and it's a much larger problem.

Under Petitioner's reading, the entire "on sale" category—indeed, the entire inquiry into whether something is a firm commercial offer to sell—is now superfluous. It is a fool's errand under Petitioner's reading to inquire into whether something is "on sale" or not because everything turns on whether the art is "available

to the public" (in some ahistorical sense; *see* Part II *supra*).

As Respondent correctly notes (Resp. Br. 36–37), under Petitioner's position, a party trying to prove that particular matter falls within the statutory language "or in public use, on sale, or otherwise available to the public" has three options. The first option is to prove that the matter is "in public use," which under Petitioner's reading requires proof that the matter is:

(i) "available to the public" *and*

(ii) "in public use" (which surely requires some proof of "use").

The second option is to prove that the matter is "on sale," which under Petitioner's reading requires proof that the matter is:

(i) "available to the public" *and*

(ii) "on sale" (which, under *Pfaff*, surely requires some proof of a commercial offer to sell).

The third option is to prove that the matter is "otherwise available to the public," which requires proof that the matter is:

(i) "available to the public."

It is easy then to see that no defendant in an infringement litigation and no party to an administrative proceeding would ever pursue the first or second options, because those merely impose requirements in addition to the requirement of proving that matter is "available to the public." Moreover, even if a defendant or other party were foolish enough to pursue the first or second options, no court or administrative deci-

sionmaker would need to decide the issues of "in public use" or "on sale" because it would immediately recognize that, if matter is "available to the public," it is prior art without regard for any additional inquiries into whether the matter was "in public use" or "on sale." The concepts of "in public use" and "on sale" would become, under Petitioner's position, entirely superfluous to the operation of § 102(a)(1).

A second contextual reason for rejecting the Petitioner's interpretation of § 102(a)(1) is that Petitioner simply assumes, without support, that (i) the phrase "available to the public" must be given a restrictive and ahistoric meaning, and (ii) this purported conflict between "available to the public" and "on sale" should be remedied by giving a restrictive reading to "on sale." A far more reasonable approach is to look to this Court's precedents to define "available to the public" broadly. That approach produces harmony, not discord, between the two phrases.

As discussed in Part II, *supra*, this Court's precedents have long defined the similar phrase "accessible to the public" broadly, not restrictively. Indeed, this Court's decision in *Bonito Boats* described pre-AIA §§ 102(a) and (b) as "operat[ing] in tandem to exclude from consideration for patent protection knowledge that is already *available to the public*." 489 U.S. at 148 (emphasis added). The "on sale" and "public use" categories of prior art were, at the time of *Bonito Boats*, contained in § 102(b), and *Bonito Boats* properly and correctly recognized that, if something falls into one of those prior art categories, it is *de jure* "available to the public" as a matter of patent law.

Bonito Boats shows that Petitioner's argument is exactly backwards: the phrase "available to the public" should not be used to impart a restrictive meaning to "on sale" and "in public use." Rather, the categories "on sale" and "in public use" should, if anything, be used in imparting a broad meaning on the undefined concept of "available to the public." The backwards nature of Petitioner's argument is also shown by its misuse of the *noscitur a sociis* canon. Petitioner assumes that, if the canon is applied in this case, the final catch-all provision should be used to *restrict* the earlier categories. Yet as precedent cited by Petitioner itself demonstrates, the canon works in the other direction: the categories in the list can be used to give an *expansive* meaning to the final catch-all phrase. A case cited by Petitioner—*United States v. United Verde Copper Co.*, 196 U.S. 207 (1905)—provides a great example.

In *United Verde Copper*, the statute authorized citizens to cut timber "for building, agricultural, mining, or other *domestic* purposes." *Id.* at 213 (emphasis in original). The government argued that the word "domestic" should be given a narrow meaning—that it should mean "household." *Id.* This Court rejected that argument. The Court interpreted the list holistically, but rather than using the final catch-all phrase "other domestic purposes" to *limit* the categories to "building, agricultural, mining," it did the reverse—it used the earlier words to reach an *expanded* definition of "domestic purposes." The Court recognized that the word "domestic" could refer not merely to the activities "of the household, but [to] those of a county, state or nation" as in the phrase "domestic manufactures." *Id.* The Court thus interpreted the word "domestic" to mean "the locality to which the statute is directed" (which

was certain mineral districts in the United States), which meant the catch-all phrase expansively authorized all "industries there practiced to use the public timber." *Id.* at 214.

The same approach makes sense in this case, especially since this Court's *Bonito Boats* decision previously used the phrase "available to the public" to refer to all of the categories of prior art in the pre-AIA version of § 102(a) and (b). In light of this Court precedent, therefore, it is far more reasonable to interpret "available to the public" in light of the well-defined category of "on sale" prior art, not the other way around.

IV. PETITIONER'S INTERPRETATION OF THE AIA RAISES A SERIOUS CONSTITUTIONAL QUESTION.

In addition to its other flaws set forth above, Petitioner's proposed interpretation of the AIA would raise a serious constitutional question; for under Petitioner's interpretation, as demonstrated by this very case, the AIA purportedly authorizes the Government to grant patents for subject matter that was in the public domain prior to the enactment of the AIA.

In *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966), this Court stated: "Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available." Although this Court has since held that in some circumstances Congress may restore copyrights for original works of authorship that enter into the public domain due to noncompliance with statutory formalities, *see Golan v. Holder*, 565 U.S. 302 (2012), the precise scope of Con-

gress's power to authorize the granting of patents for subject matter that is not "new," and thus not patent-eligible, remains uncertain. The statutory interpretation advanced by Petitioner thus raises a serious constitutional question concerning the scope of congressional power to grant patent rights on technologies that are already in the public domain.

The facts of this case are a good example. As Petitioner has conceded, its alleged invention was "on sale," within the meaning of then-existing law, more than one year before the date when it filed its patent application (in January 30, 2003). Thus, at the time of the filing of Petitioner's priority patent application, the alleged invention had fallen into the public domain by operation of then existing law.

Under Petitioner's view, Congress's enactment of the AIA in 2011 gave Petitioner the extraordinary opportunity to file a new patent application in 2013 that could generate patent rights on a technology that had been in the public domain for more than a decade. That extraordinary opportunity arose, under Petitioner's view, because (i) the AIA supposedly constricted the scope of the "on sale" prior art category by adding the new "otherwise available to the public" prior art category, and (ii) the AIA's transition rule gave parties with still pending patent applications an ability to have the new version of § 102 apply if they undertook the maneuver that Petitioner did in this case.[3]

---

[3] The AIA's transition rule provides that the new version of § 102 applies to the whole of an "application for patent" that "contains or contained at any time" at least one claim that has an "effective filing date" after the effective date of the AIA. *See* Leahy–Smith

The transition rule in § 3(n) the AIA permits an applicant with a pending patent application to add new subject matter and new claims with a post-AIA priority date and thereby to have the application subjected to the new version of § 102. While somewhat complicated, the transition rule in § 3(n) of the AIA is clear enough on that point. But given that transition rule, the issue in this case is whether it is reasonable to interpret the AIA's addition of the new category of prior art ("otherwise available to the public") as working a wholesale constriction on preexisting categories of prior art so that parties may obtain patent rights on matters that previously were in the public domain.

America Invents Act, § 3(n), Pub. L. No. 112-29, 125 Stat. 284, 293. The statutory effective date of the AIA was 18 months after the statute was enacted (*see id.*), which was March 16, 2013 (*see id.* at 341). Approximately two months after the AIA's effective date (on May 23, 2013), Petitioner filed what is called a "continuation-in-part" or CIP application. *See* J.A. 435. Such applications are entitled to maintain their priority of filing based on an earlier application but are also allowed to include "new matter" that was not in the earlier application (*see* 37 C.F.R. § 1.53(b)(2)). Claims based on the "new matter" are required to use as their "effective filing date" the new filing date of the CIP application, but all other claims may still use as their effective filing date the time of filing of the earlier application.

Petitioner's 2013 CIP application included as "new matter" an "Example 8" (J.A. 483–84) comprising a 0.75 mg dose of the same pharmaceutical composition as was disclosed in its earlier patent applications. Although the patent that Petitioner obtained on its 2013 CIP application—i.e., the patent relevant to this case—no longer claims the Example 8 composition, the temporary presence of a claim directed to Example 8 allowed Petitioner to assert that the whole of its 2013 application should be evaluated under the new version of § 102 enacted by the AIA.

Because that result raises a serious constitutional issue, the canon of constitutional avoidance supplies the answer: such an interpretation should be resisted if there is a reasonable alternative interpretation of the language. In this case, that interpretation is easy to discern: if the additional category of prior art added by the AIA is interpreted as merely an addition, not a subtraction, then no constitutional issue arises. Parties with patent applications pending at the time of the enactment of the AIA could do as Petitioner in this case has done and have the new version of § 102 apply, but it will not allow them to patent what was already in the public domain.

That approach is especially sensible given that *Golan* and this Court's earlier decision in *Eldred v. Ashcroft*, 537 U.S. 186, 202 n.7 (2003), interpreted *Graham*'s teaching as concerning "an invention's very eligibility for patent protection." 565 U.S. at 324 (quoting *Eldred*). That interpretation of the statement in *Graham* meant that the case had no applicability to the issues in *Golan* and *Eldred* because those cases dealt with original works whose copyright-eligibility was not in question. This case, in contrast, does involve a claimed invention's "very eligibility" for patent protection under 35 U.S.C. §§ 101 and 102(a).

Moreover, both *Golan* and *Eldred* recognized limits on congressional power retroactively to grant or extend copyrights. Over dissents in both cases, the Court found that those limits were not exceeded under the circumstances of those cases because Congress could rationally have concluded that the retroactive copyright grants or extensions promoted constitutionally permissible ends. *See Eldred*, 537 U.S. at 207–08, 215 (holding

that, in light of congressional findings, Congress could rationally have found that the extension of existing terms advanced constitutionally permissible goals); *Golan*, 565 U.S. at 332.

The Court's analysis in *Golan* demonstrates that, even for copyrights, the grant of intellectual property rights over matters in the public domain requires constitutional scrutiny. Such grants should not be presumed to have been authorized where there is no apparent congressional recognition that such an extraordinary result was being reached. *See Golan*, 565 U.S. at 320 (noting that "[u]ndoubtedly, federal copyright legislation generally has not affected works in the public domain"); *id.* at 362 (Breyer, J., dissenting; joined by Alito, J.) (noting that "Congressional practice . . . consists of a virtually unbroken string of legislation preventing the withdrawal of works from the public domain").

CONCLUSION

The judgment of the Court of Appeals should be affirmed.

Dated: October 16, 2018

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No. 17-1229

IN THE

Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC. AND TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICUS CURIAE* US INVENTOR, INC. IN SUPPORT OF PETITIONER HELSINN HEALTHCARE S.A.

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I. Interests of *Amicus Curiae* US Inventor, Inc.[1]

US Inventor, Inc. ("US Inventor") is a non-profit association of inventors devoted to protecting the intellectual property of individuals and small companies. It represents its 13,000 inventor and business members by promoting strong intellectual property rights and a predictable U.S. patent system through education, advocacy, and reform.

US Inventor was founded to support the innovation efforts of the "little guy" inventors, seeking to ensure that strong patent rights are available to support their efforts to develop their inventions, bring those inventions to a point where they can be commercialized, create jobs and industries, and promote continued innovation. Its members consist of individual inventors and small- to medium-sized enterprises that depend heavily on the value created by meaningful patent rights. Their broad experience with the patent system, new technologies, and creating companies, gives them a unique perspective on the important issues presented in this appeal.

II. Summary of the Argument

The Federal Circuit has decided an important question of law in a way that conflicts with the plain

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1. Pursuant to Supreme Court Rule 37, amicus US Inventor certifies as follows: All parties to this matter have provided written consent to the filing of this amicus curiae brief. No counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund preparing or submitting this brief. No person or entity, other than amicus, its members, or its counsel, contributed money intended to fund preparing or submitting this brief.

language of § 102(a)(1) of the America Invents Act ("AIA"), conflicts with the legislative history and purpose of the changed statutory language, conflicts with the USPTO's interpretation of the statute, conflicts with the established canons of statutory construction, conflicts with sound policy, and is otherwise unsupported. New AIA § 102(a)(1) should have been construed as a whole, based on its clear and unequivocal text, to require that "on sale" prior art must be "available to the public." The Federal Circuit did not do that.

The Federal Circuit's *Helsinn* opinion has thrown the "bath water" in with the "baby," importing pre-AIA case law into new AIA § 102(a)(1), despite the inconsistency of that case law with the plain language of the new statute. The *Helsinn* court's interpretation of § 102(a)(1) also newly encompasses foreign "secret sales" as invalidating prior art for the first time in history. Further, the Federal Circuit has created new law, announcing an "existence of sale" prior art bar, which is not supported by either the language of the new statute or its legislative history.

This brief seeks to address aspects of this erroneous and detrimental opinion in addition to those pointed out in Petitioner's brief, in an effort to assist the Court in its consideration of the important issues at stake. If allowed to stand, the *Helsinn* opinion will have a severe and disproportionate impact on the small U.S. inventor—the life and blood of our economy—whose interests our patent law system is supposed to foster and protect.

Small inventors often lack the resources or manufacturing ability to develop their inventions themselves. They rely on development arrangements

and seed funding to pay for the significant costs of patent prosecution and of engaging in further experimentation, discovery, and invention development. They need to be able to rely on their intellectual property rights as a basis for attracting businesses that may be interested in those innovations, and in partnering, collaborating, or investing in them. To do that, they must be allowed to confidentially disclose the nature of those inventions without jeopardizing their patent rights, and include those rights in confidential transactions. The "secret sale" trap for the unwary small inventor jeopardizes their all-important patent rights.

The plain text of AIA § 102(a)(1) requires that the claimed invention must be available to the public in order for the on sale bar to apply, and thus does not encompass secret sales. Moreover, even if the statute were ambiguous, the legislative history consistently confirms this construction.

Over time, different approaches to statutory construction have waxed and waned. This case, however, is non-tide-sensitive. Both the plain language of the statute and the legislative history cohesively require that in order for a sale to qualify as invalidating prior art, it must make the claimed invention available to the public.

The Federal Circuit also accorded the wrong rank to the available legislative history. The Federal Circuit ignored both the Senate Committee Report, which adopted the statutory language at issue, and the House Committee Report, which embraced that language and explained the policies behind it. The court instead focused on floor statements, impugning their reliability

with regard to determining Congress's intent. Moreover, contrary to the Federal Circuit's criticism of the floor statements as "after the fact," the Committee Reports explained the reasoning behind and the meaning of the statutory language before votes were taken.

A fair construction should be adopted here. Nothing in the plain statutory text, nor in the legislative history, nor in any case law of this Court since the *Pennock* days,[2] would support construing the new statute to invalidate U.S. patents based on "secret sales" (now including secret foreign sales), which do not make the claimed invention available to the public. Such a construction should not be adopted.

Teva has taken the position that "on sale" should keep its "historical" meaning. Words and phrases, however, must be read and construed in the context of the complete statutory provision in which they appear. The statute must be read as a whole. This is particularly important here, where the statute itself is comparatively short, and both the wording and the punctuation of this statute were purposely changed. The statute as a whole evidences that Congress intended the statute to have a different meaning.

The Federal Circuit indicated that its finding that the "on sale" bar applied was limited to the "particular Supply and Purchase Agreement" before it. That finding, however, necessarily turned on the court's conclusion that "if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale" in order for the "on sale" bar to apply. *Helsinn*

2. *Pennock v. Dialogue*, 27 U.S. 1 (1829).

Healthcare S.A. v. Teva Pharm. USA, Inc., 855 F.3d 1356, 1371 (Fed. Cir. 2017). That broad construction of the "on sale" bar is directly contrary to the plain meaning of 35 U.S.C. § 102(a)(1), contrary to its purpose, contrary to its legislative history, and would defeat the efforts of the House and the Senate to harmonize the U.S. view of what counts as prior art with the views of the rest of the world.

All of the foregoing considerations point to a construction under which "secret sales" are not invalidating prior art under post-AIA § 102(a)(1). Under post-AIA § 102(a)(1), "prior art" cannot be invalidating prior art unless it made the claimed invention available to the public.

III. Argument

A. The Federal Circuit's Interpretation of Section 102(a)(1) Is Contrary to the Purpose of the AIA and Destroys Harmony with Foreign Law.

As Petitioner notes in its merits brief, a key consideration underlying enactment of the AIA was the conversion of the American patent system from a "first-to-invent" to a "first-inventor-to-file" system, thereby taking a major step towards harmonizing the American patent system with the systems of other leading industrialized countries around the world. *See* Brief for the Petitioner (Aug. 23, 2018) ("Pet. Br.") at 5-6. Congress recognized that it is "common for inventors and companies to file for protection in several countries at the same time." H.R. Rep. No. 112–98, 112th Cong., 1st Sess. (June 1, 2011) ("AIA Committee Report") at 41. An important goal of international harmonization was to eliminate the need

for patent applicants to comply with multiple incompatible patent systems.

As part of that harmonization, Congress redefined the scope of invalidating prior art under § 102 as follows:

> A person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, *or* in public use, on sale, *or otherwise available to the public* before the effective filing date of the claimed invention ....

AIA 35 U.S.C. § 102(a)(1) (emphasis added).[3]

A primary purpose of the "on-sale" bar is to "exclude from consideration for patent protection knowledge that is *already available to the public*" on the grounds that "the creation of a monopoly in such information would not only serve no socially useful purpose, but would in fact injure the public by *removing* existing knowledge from public use." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989) (emphasis added). By enacting the AIA and making explicit the requirement that prior art make the claimed invention available to the public to qualify as potentially invalidating prior art, Congress affirmed that longstanding purpose.

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3. The redefinition of the scope of prior art is only one of the significant changes wrought by the AIA. For a comprehensive list of those changes, see R.A. Armitage, *Understanding the America Invents Act and Its Implications for Patenting*, 40 AIPLA Q. J. 1, 10-14 (2012).

Construing AIA § 102(a)(1) as excluding as prior art sales that have not made the invention "available to the public" also comports with the AIA's overarching goal of "harmonizing our system for granting patents with the best parts of other major patent systems throughout the industrialized world." AIA Committee Report at 39. No other major industrialized nation defines invalidating prior art as encompassing secret sales. *See, e.g.*, Brief for The Naples Roundtable, Inc. as Amicus Curiae Supporting Plaintiffs-Appellees, *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017) (Nos. 2016-1284, 2016-1287), at 6-13. Interpreting the on-sale bar to encompass secret sales would undermine Congress's goal of ensuring that what counts as prior art under American law is consistent with prior art recognized by other nations.

Before the AIA was enacted, an invention that was "in public use" or "on sale" precluded the grant of a patent only if such public use or sale occurred "in this country." Pre-AIA 35 U.S.C. § 102(b). Prior art now encompasses "all art that *publicly exists* prior to the filing date" regardless of geographical location. AIA Committee Report at 42 (emphasis added). This geographical expansion is interconnected with the limitation of prior art to the categories of *publicly available* materials listed in § 102(a)(1), including those "in public use" or "on sale." Both the geographical expansion and the restriction of prior art to publicly available materials harmonize U.S. law with foreign law regarding the bases for invalidity. The Federal Circuit opinion, which did not address either the AIA Committee Report for the enacted version of the AIA, or the previous Senate Judiciary Committee Report which proposed and explained the language at issue,

utterly defeats a major purpose of Congress in enacting § 102(a)(1), and would put the United States, once again, out of step with the rest of the world.

B. The "Little Guy" Stands to Bear a Disproportionate and the Most Destructive Brunt of this "On Sale" Bar Storm.

The small inventor is the true representative of the culture of innovation and ingenuity that Article I, Section 8, Clause 8 of the Constitution was meant to promote and foster. The Federal Circuit's *Helsinn* opinion effects a direct hit on this country's grassroots inventive ethos by disincentivizing the risk-taking and experimentation that are inherent in the inventive process, and creating uncertainty with respect to development and commercialization of inventions.[4]

The *Helsinn* opinion is especially problematic because it comes at a time when the United States is facing a true crisis in innovation. Countries that were once net importers of advances in technology are now eclipsing the United States with respect to advances in the industries of the future. For example, in 2017, China accounted for 48% of the world's total artificial intelligence startup funding, while the United States accounted for only 38%.[5] China

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4. *See generally* P. Morinville, "Crisis in American Innovation," US Inventor, *available at* http://www.usinventor.org/wp-content/uploads/2017/08/USI-Crisis-in-American-Innovation-Full-Version.pdf.

5. *See* J. Vincent, "China overtakes US in AI startup funding with a focus on facial recognition and chips," at 1, *available at* https://www.theverge.com/2018/2/22/17039696/china-us-ai-funding-startup-comparison.

is either already leading or is becoming the world leader in quantum computing, solar cells, and other technologies that provide the foundation for several important industries, including advanced energy production and globalized currencies.[6] These changes are reflected in the significant difference in the number of patent applications between the two countries: by 2015 nearly twice as many patent applications were filed in China (1,101,864) as were filed in the United States (589,410).[7] In the first quarter of 2017, the number of angel and seed stage funding rounds in the United States dropped by 62 percent.[8] Entrepreneurs have found it harder and harder to raise money through venture capital.[9]

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6. *See* J. Pekkanen, "China Leads the Quantum Race While the West Plays Catch Up," at 2, *available at* https://www.forbes.com/sites/saadiampekkanen/2016/09/30/china-leads-the-quantum-race-while-the-west-plays-catchup/#b14212592856; M. Meng, "With high-performance cells, China takes aim at high-end solar market," *available at* https://www.reuters.com/article/us-china-solar-cost-analysis/with-high-performance-cells-china-takes-aim-at-high-end-solar-market-idUSKCN1BP0X6.

7. WIPO, "Global Patent Applications Rose to 2.9 Million in 2015 on Strong Growth from China; Demand Also Increased for Other Intellectual Property Rights," at 1, *available at* http://www.wipo.int/pressroom/en/articles/2016/article_0017.html.

8. *See* M. Kendall, "Silicon Valley investing slump continues, fewer startups get funded," at 4, *available at* https://www.siliconvalley.com/2017/04/04/silicon-valley-investing-slump-continues-fewer-startups-get-funded/.

9. *Id.*

Indeed, some ninety percent of all startups in the United States fail,[10] and lack of funding is consistently cited as a significant cause of that failure.[11] Lack of patent protection is, in turn, a major contributor to the inability to get funding.[12] Scholars from the Harvard Business School, New York University's Stern School of Business, and the National Bureau of Economic Research recently undertook a study of the incremental value of patents to startups in the United States.[13] The authors define the incremental value of a patent as "the incremental return generated by the patent, beyond what could be earned if the invention were not granted a patent."[14]

The researchers concluded that obtaining patent protection has a dramatic effect on a startup's likelihood of success. They estimated that "[f]or the average startup in our sample, . . . receiving a patent leads to 16 additional

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10. T. Clark, "Why do so many startups fail?" Forbes Magazine (March 19, 2015) available at https://www.forbes.com/sites/sap/2015/05/19/why-do-so-many-start-ups-fail/#18b823755873.

11. V. Lance, "Top 20 Reasons Why Startups Fail," Forbes Magazine (March 2, 2015) available at https://www.forbes.com/sites/groupthink/2016/03/02/top-20-reasons-why-startups-fail-infographic/#5502dc823911.

12. T. Clark, "Why do so many startups fail?" available at https://www.forbes.com/sites/sap/2015/05/19/why-do-so-many-start-ups-fail/#18b823755873.

13. S. Farre-Mensa, et al., "What Is a Patent Worth? Evidence from the U.S. Patent 'Lottery'" (March 14, 2017), USPTO Economic Working Paper 2015-5, available at SSRN: https://ssrn.com/abstract=2704028 or http://dx.doi.org/10.2139/ssrn.2704028.

14. *Id.* at 1-2.

employees after five years, and $10.6 million in additional sales cumulated over five years. . . ." *Id.* at 4. They further concluded that:

> [a] first patent grant also increases both the number of subsequent patents the firm is granted (by 49%) and their quality (with the average number of citations per subsequent patent increasing by 26%). Patent approvals appear to have a particularly strong effect on sales growth and follow-on innovation for startups in the IT sector—a result that contrasts with prior survey evidence that large IT firms consider patents to be among the least effective mechanisms to ensure the profitability of their R&D investments.

Id. (internal citation omitted).

The researchers explained that these dramatic effects are, in turn, attributable to one critical factor—patent protection. A patent grant means the startup's chances of getting funding grow substantially:

> We find that a patent grant increases a startup's chances of securing funding from [venture capital] by 47%, and of securing a loan by pledging the patent as collateral by 76%, within three years of the patent decision. A patent grant also more than doubles the odds of the startup raising funding from public investors through an IPO. . . . [P]atent grants facilitate startups' access to external finance in contexts where information frictions, and thus

> contractual hazards, are high. A patent grant sets a startup on a growth path through funding that helps transform its ideas into products and services that generate jobs, revenues, and follow-on inventions.

Id.

Other research has led to similar findings. With regard to start-up biopharmaceutical innovation, for example, "[p]atents play an essential role in the economic 'ecosystem' of discovery and investment. . . ." H. Grabowski, et al., ***The Role of Patents and Research and Development Incentives in Biopharmaceutical Innovation***, Intellectual Prop. & Innov. (Feb. 2015). Moreover, "the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms." *Id.*

Small inventors might not be able to develop their intellectual property from nascent conception to a fully developed product that can contribute to society without funding and assistance from a partner in the pertinent industry. Further, they might not be able to develop their intellectual property itself, and pursue protection of it, without partners. Similarly, as in *Helsinn*, the invention at issue might have enormous promise, but there may be multiple different embodiments of the invention, and research and development resources may be necessary to develop and define the invention.

If allowed to stand, the Federal Circuit's opinion in *Helsinn* will cause significant irreparable harm to small inventors, including by making it much harder for them to get their inventions patented, and get the funding they

need to develop their inventions and bring them to market. This, in turn, will have negative consequences for our economic well-being as a whole, because small inventors are critical to the innovation ecosystem. As of about a decade ago, small businesses hired 43 percent of America's high tech workers (e.g., scientists, engineers, computer programmers), produced 16.5 times more patents per employee than large patenting firms, generated 65 percent of net new jobs over the previous 17 years, and made up 97.5 percent of all identified U.S. exporters.[15]

Confidential inclusion of patent rights as part of a transaction is an essential step in enabling a small inventor to bring an invention from its conception to the point where it becomes a contribution to society. Trial and error are inherent in the innovation process, and significant work may only yield a small amount of patentable and commercially viable matter. If inventors cannot disclose their inventions under confidentiality agreements as part of their business development transactions without fear that they are thereby placing the patentability of those inventions in jeopardy, future innovation, collaboration, and development will be severely chilled.

This is especially true when inventions are being developed by smaller companies, where an agreement with another company to fund or share the costs of development may rise to the level of materiality under Security and Exchange Commission ("SEC") laws, and thus obligate such companies to disclose the agreement

15. Small Business Administration, Office of Advocacy: The Voice of Small Business in Government (updated Jan. 2011), *available at* https://www.sba.gov/sites/default/files/sbfaq.pdf.

in their public filings. *See* 17 C.F.R. § 240.12b-2 (SEC defining "material" as those matters to which there is a substantial likelihood that a reasonable investor would attach importance in determining whether to buy or sell the securities registered). This means that the materiality threshold for including information in the SEC filings of a million-dollar company is far lower than it is for a billion-dollar company—small businesses have to disclose much smaller transactions to comply with the SEC's materiality requirement than large businesses do. Small businesses also will face difficulty in attracting and co-developing or acquiring rights to inventive ideas for development and public benefit.

In the pharmaceutical industry, drug development typically requires many years and billions of dollars.[16] In order for smaller companies to participate in the drug development process, they necessarily must partner with larger companies or venture capital funding sources. If a conveyance of rights under the invention is included as part of the collaboration agreement such that it qualifies as a "sale," *Helsinn* would render that agreement invalidating prior art, even if the invention itself is not disclosed to, or otherwise put in the hands of, the public.

The Federal Circuit also injected uncertainty and unpredictability into a judicially created "existence of sale" bar by making statements such as, "We do not find that distribution agreements will always be invalidating

16. *See* Tufts Center for the Study of Drug Development (CSDD), "Tufts CSDD Assessment of Cost to Develop and Win Marketing Approval for a New Drug Now Published," *available at* http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published.

under § 102(b). We simply find that this particular Supply and Purchase Agreement is." *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017). That particular Supply and Purchase Agreement, however, was redacted, and did not disclose the claimed invention. *Helsinn*, 855 F.3d at 1361-62.

The Federal Circuit has created a Hobson's choice for the small inventor, both alternatives of which are detrimental to innovation and against the public interest: collaborate and develop your invention but give up your patent rights by doing so (thus killing the invention, and keeping the public from benefiting from it in the process), or patent it but do not enter into the agreements necessary to develop it, and thus leave it and the patent sitting on a shelf (thus killing the invention, and keeping the public from benefiting from it in the process).

The Federal Circuit's interpretation of the scope of prior art also inherently creates uncertainty because it includes patent-defeating secret sales that may have taken place anywhere in the world. That interpretation makes investing in innovation much riskier and therefore much more costly. The ability to ascertain what exists as invalidating prior art is of critical importance in our patent system. All participants in the patent system—inventors trying to develop their inventions and seeking partners to do so, companies deciding to enforce their own patents or to license or acquire patents from others, and investors valuing the patent portfolios of potential investment targets—must be able to determine what constitutes potentially invalidating prior art under the AIA. An explicit objective of the AIA was to "establish a more efficient and streamlined patent system that

will improve patent quality and limit unnecessary and counterproductive litigation costs." AIA Committee Report at 40.

Encompassing worldwide "secret sales" grossly and unsupportably expands what qualifies as prior art under the AIA, and thus greatly increases uncertainty and unreliability, rather than effecting the streamlining that was one of the AIA's overarching goals. The ability to ascertain what prior art exists informs participants' decisions about how best to invest their resources, and whether or not to invest in innovation. Encompassing "secret sales" within the scope of § 102(a)(1) undermines such efforts.

Small inventors face numerous challenges and obstacles these days, and a dependable and clear patent protection framework is an essential foundation for them to be able to survive and thrive. They need this Court to reverse the *Helsinn* opinion, before it and its progeny cause irreparable damage.

C. The Federal Circuit's Opinion Is Contrary to the Plain Language of the Statute.

"As with any question of statutory interpretation, [the Court's] analysis begins with the plain language of the statute." *Jimenez v. Quarterman*, 555 U.S. 113, 118 (2009) (citation omitted). It is well settled that when interpreting a statute, one must begin with "the assumption that the ordinary meaning of the language chosen by Congress accurately expresses the legislative purpose." *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 101 (2011) (internal quotation marks, modification, and citation omitted).

A "cardinal rule" of statutory construction is "that a statute is to be read as a whole." *Corley v. United States*, 556 U.S. 303, 314 n.5 (2009) (emphasis added) (quoting *King v. St. Vincent's Hospital*, 502 U.S. 215, 221 (1991)); *see also Samantar v. Yousuf*, 560 U.S. 305, 319 (2010) ("[W]e do not . . . construe statutory phrases in isolation; we read statutes as a whole." (quoting *United States v. Morton*, 467 U.S. 822, 828 (1984))). Here, the meaning of "on sale" must be construed in the context of the language of new AIA § 102(a)(1) as a whole.[17] The ordinary meaning of § 102(a)(1) of the AIA requires that a sale of a claimed invention make the "claimed invention" "available to the public" in order for the sale to qualify as invalidating prior art. "Patented," "described in a printed publication," "public use," and "on sale" are all specific circumstances in which the "claimed invention" can be made "available to the public." The catchall category, "or otherwise available to the public," coming as it does at the end of the list of those prior art categories, then encompasses other ways in which the invention can be made "available to the public," and confirms that the terms preceding it—including the term "on sale"—also involve making the invention "available to the public."

Webster's Third New International Dictionary defines "otherwise" as "in a different way or another manner." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1598 (2002). In order for a claimed invention to become "available to the public" in a "different way or manner,"

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17. Instead of focusing on the language of the new statute as a whole, in its Brief in Opposition to Certiorari ("Opp. Br."), Teva did the opposite, and attempted to import what it characterizes as the "historical" meaning of "on sale" as encompassing "secret sales." *See* Opp. Br. at 1.

there must be a referenced "way or manner" in which the invention is "available to the public."

In plain English, "or otherwise available to the public" means "or *in other ways* available to the public." The use of the "or otherwise" clause thus linguistically signals that the "on sale" activity—like the other activities enumerated in the provision—must make the claimed invention "available to the public." This Court made a similar observation in *United States v. Standard Brewery, Inc.*, 251 U.S. 210, 217-18 (1920), rejecting the government's position that a statute prohibiting products for making "beer, wine, or other intoxicating malt or vinous liquor for beverage purposes" encompassed "beer and wine whether intoxicating or not," and concluding that the provision aimed "only at intoxicating beverages." Any other interpretation of the statutory text would ignore or render superfluous the term "or otherwise."

A contrary interpretation also would ignore the term "available to the public." Requiring that the claimed invention be "available to the public" necessarily requires that the public have access to the claimed invention. Indeed, as Congressman Smith, one of the AIA's sponsors, explained in his amicus brief:

> The changes to the law arising from the drafting of new § 102's "prior art" provision involved retiring the phrase "known or used" from repealed § 102(a)'s definition of prior art, *notwithstanding that this phrase had been used to define "prior art" in every patent statute since 1790.* It was replaced with an alter ego term, "available to the public."

> This new terminology is used internationally to define prior art, in part by excluding confidential or otherwise secret subject matter from qualifying as prior art.

Brief for Amicus Curiae Congressman Lamar Smith in Support of Petitioner, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc., et al.*, (No. 17-1229) (Aug. 23, 2018) at 2 (emphasis added).[18]

Ignoring "otherwise" and "available to the public" violates "one of the most basic interpretive canons—that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (internal quotation marks, modification, and citation omitted). Indeed, this Court has long recognized that it is "not at liberty to construe any statute so as to deny effect to any part of its language." *Market Co. v. Hoffman*, 101 U.S. 112, 115-16 (1879). The "or otherwise" and "available to the public" language is in the statute for a reason. The *Helsinn* opinion effectively erases that language from the statute.

Interpreting "on sale" to encompass secret sales would also be contrary to the most natural reading of the text. There is no dispute that the first three categories of prior art listed in § 102(a)(1)—inventions that are "patented," "described in printed publications," or "in public use"—

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18. The fact that one of the actual sponsors of the AIA has filed several amicus briefs on the issue is notable; it is not often that the Court has the opportunity for such direct insight into a statute's legislative history.

describe prior art that is publicly accessible. "In public use" and "on sale" both follow the ", or" that Congress added after "printed publication"—which deliberately set off the language: "or in public use, on sale, or otherwise available to the public." Given that the penultimate category of prior art—inventions that are "on sale"—is followed by the catchall category, "or otherwise available to the public," it stands to reason that, like the three preceding categories of prior art, and like the subsequent catchall category, sales also have to make the invention publicly accessible in order to qualify as potentially invalidating prior art. The statute was written so that all five categories share the commonality of being "available to the public."

The most natural and only reasonable interpretation of the language that Congress chose is that the "claimed invention" that is "on sale" must be "available to the public" in order for the "sale" to be invalidating prior art. The term "otherwise" and the comma before the phrase "or otherwise available to the public" do not leave room for any other reasonable interpretation.

D. The Federal Circuit's Opinion Is Contrary to the Legislative History of § 102(a).

If a statute is perceived to be ambiguous, the legislative history of that statute should be considered. Here, the Federal Circuit did not appropriately do that. The Federal Circuit did not accord the available legislative history the right rank in the hierarchy of materials available for consideration in its statutory analysis. Here, the Federal Circuit disregarded the insights available through the highest ranking available legislative history: the Committee Reports.

The House Committee Report accompanying the AIA could hardly be clearer that Congress intended to redefine the scope of invalidating prior art to exclude art that was not publicly available: "[p]rior art will be measured from the filing date of the application and will typically include all art that *publicly exists* prior to the filing date, other than disclosures by the inventor within 1 year of filing." AIA Committee Report at 42 (emphasis added). The Report explains: "Thus, in section 102 the 'in this country' limitation as applied to 'public use' and 'on sale' is removed, and the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to *emphasize the fact that it must be publicly available*." *Id.* at 42-43 (emphasis added); *see also* S. Rep. No. 111-18, 111th Cong., 1st Sess. at 6 (May 12, 2009). It is remarkable that the Federal Circuit never considered or mentioned either the Senate Judiciary Committee Report, which was the source of the language at issue, or the House AIA Committee Report.

The Court has recognized that statements in Committee Reports are "the authoritative source for finding the Legislature's intent" because "the Committee Reports on the bill . . . represent the considered and collective understanding of those [members of Congress] involved in drafting and studying proposed legislation." *Eldred v. Ashcroft*, 537 U.S. 186, 209 n.16 (2003) (quoting *Garcia v. United States*, 469 U.S. 70, 76 (1984)) (internal quotation marks omitted). "[T]hese materials 'have long been important means of informing the whole chamber about proposed legislation,' . . . a point Members [of Congress] themselves have emphasized over the years. It is thus no surprise that legislative staffers view committee and conference reports as the most reliable type of

legislative history." *Digital Realty Tr., Inc. v. Somers*, 138 S. Ct. 767, 782-83 (2018) (Sotomayor, J., concurring) (quoting A. Gluck, et al., *Statutory Interpretation from the Inside—An Empirical Study of Congressional Drafting, Delegation and the Canons: Part I*, 65 Stan. L. Rev. 901, 977 (2013)).

The theme of public availability was reiterated by Senator Kyl on March 8, 2011, when he explained that Congress chose the word "otherwise" to "make[] clear that the preceding clauses describe things that are of the same quality or nature as the final clause—that is, although different categories of prior art are listed, all of them are limited to that which makes the invention 'available to the public.'" 157 Cong. Rec. S1368, S1370 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (cited in final Committee Report, H.R. Rep. No. 112-98, at 43 n.20 (June 1, 2011)). In a hearing on the final bill on September 8, 2011, Senator Kyl again observed:

> As Chairman Smith most recently explained in his June 22 remarks, "contrary to current precedent, in order to trigger the bar in new 102(a) in our legislation, an action must make the patented subject matter 'available to the public' before the effective filing date." . . . When the committee included the words "or otherwise available to the public" in section 102(a), the word "otherwise" made clear that the preceding items are things that are of the same quality or nature. As a result, the preceding events and things are limited to those that make the invention "available to the public."

157 Cong. Rec. S5431 (daily ed. September 8, 2011) (statement of Sen. Kyl) (quoting 157 Cong. Rec. H4429 (daily ed. June 22, 2011) (statement of Rep. Smith, lead sponsor of House AIA bill, H.R. 1249)).

A few years earlier, Senator Kyl had explained that the purpose of "eliminating confidential sales and other secret activities as grounds for invalidity and imposing a general standard of public availability" was to "make the patent system simpler and more transparent," which change, in turn, will "provide greater certainty and predictability—it should also substantially reduce the need for discovery in patent litigation, since defendants will no longer need to uncover evidence of private sales or offers for sale or other nonpublic information in order to determine whether the patent is valid." 154 Cong. Rec. S9992 (daily ed. Sept. 27, 2008) (statement of Sen. Kyl).

Statements in the AIA's legislative history by "the sponsor[s] of the language ultimately enacted, are an authoritative guide to the statute's construction." *See N. Haven Bd. of Educ. v. Bell*, 456 U.S. 512, 526-27 (1982) (collecting cases); *see also Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 585 (1988) ("It is the sponsors that we look to when the meaning of the statutory words is in doubt."); *Bowsher v. Merck & Co.*, 460 U.S. 824, 831-33 (1983) ("The only explanation in the legislative history of the meaning and purpose of the amendment is that of [a sponsor]. His statement, which, as the explanation of the sponsor of the language, is an 'authoritative guide to the statute's construction. . . .'") (quoting *N. Haven Bd. of Educ.*, 456 U.S. at 527)); *Schwegmann Bros. v. Calvert Distillers Corp.*, 341 U.S. 384, 394-95 (1951).

The Federal Circuit's statement that "floor statements are typically not reliable as indicators of congressional intent," and its citation to *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546 (2005), are inapposite. *See Helsinn*, 855 F.3d at 1368. The legislative history at issue in *Exxon* is not comparable to the relevant legislative history of the AIA. In *Exxon*, Committee Reports conflicted regarding the correct statutory language interpretation at issue. *Id.* at 569-70. Here, all Committee Reports are in agreement with regard to the meaning of the language at issue. Moreover, in *Exxon*, the Court rejected one interpretation where three law professors who had participated in drafting the statute acknowledged in a journal essay that (1) the plain text of the statute was contrary to the rejected interpretation, and (2) the rejected interpretation "in the House Report was a *post hoc* attempt to alter that result." *Id.* Again, no such circumstances exist here, where Petitioner's interpretation follows the plain statutory language, and the legislative history for the AIA consistently supports that interpretation. Indeed, the Court has previously concluded that *Exxon* does not counsel against a party's interpretation where the legislative history supports only one—in this case, Petitioner's—interpretation of the statutory language at issue. *See Mohamad v. Palestinian Auth.*, 566 U.S. 449, 459-60 (2012) (observing that "limitations of th[e] drafting history" did not overcome the fact that "the sole explanation for [the statutory language] . . . confirms what we have concluded from the text alone").

The suggestion that Congress either was not aware of how it was revising the scope of invalidating prior art, or was not aware of the consequences its changes would have, *Helsinn*, 855 F.3d at 1371, is untenable. Congress

intended to revise the scope of invalidating prior art so that it did not encompass secret sales; the language it chose "accurately expresses [its] legislative purpose." *Microsoft*, 564 U.S. at 101.

E. The Federal Circuit's Opinion Is Contrary to the USPTO Interpretation and Guidelines.

Based on its review of the statutory text and the legislative history, the U.S. Patent and Trademark Office ("USPTO") concluded that the AIA requires that sales under § 102(a)(1) must be publicly available: "[t]he phrase 'on sale' in AIA 35 U.S.C. 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA 35 U.S.C. 102(b), *except that the sale must make the invention available to the public.*" Examination Guidelines for Implementing the First Inventor to File Provisions of the Leahy-Smith America Invents Act, 78 Fed. Reg. 11059, 11075 (Feb. 14, 2013) (emphasis added).

"These examination guidelines indicate that the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art . . . [and] that an activity (such as a sale, offer for sale, or other commercial activity) is secret (non-public) if, for example, it is among individuals having an obligation of confidentiality to the inventor." *Id.* at 11060. The USPTO explained that "[r]esidual clauses such as 'or otherwise' or 'or other' are generally viewed as modifying the preceding phrase or phrases," and that "[t]herefore, the Office views the 'or otherwise available to the public' residual clause of the AIA's 35 U.S.C. 102(a)(1) as indicating that secret sale or use activity does not qualify as prior art." *Id.* at

11062 (citations omitted). It also noted "that the Office's interpretation is consistent with the interpretation that was clearly expressed by the bicameral sponsors of the AIA during the congressional deliberations on the measure." *Id.* (citations omitted). Indeed, in considering the "on sale" language in the context of the "or otherwise available to the public" language, the USPTO's interpretation is in keeping with the "cardinal rule" that the statute is to be "read as a whole."

The USPTO also observed that some commentators said that "interpreting the 'on sale' provision to require public availability is good public policy in that it would lower litigation costs by simplifying discovery, and would reduce unexpected prior art pitfalls for inventors who are not well versed in the law." *Id.*

The USPTO's interpretation not only is the most natural reading of the statute, but also reflects close attention to the statute's legislative history.

F. The Federal Circuit's Opinion Is Inconsistent with Established Canons of Statutory Construction.

1. Noscitur a Sociis: The "On Sale" Bar Reflects the "Company It Keeps."

Even if § 102 were ambiguous (which it is not), established canons of construction support interpreting the "on sale" bar as requiring that an invalidating sale must make the claimed invention publicly available. As Petitioner notes in its brief, under the noscitur a sociis canon of statutory construction, "words in a statute

are known by the company [they] keep[]." Pet. Br. at 20 (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995)).

The rule of noscitur a sociis (or the associated-words canon) "is a rule of construction to be applied where there is doubt and ambiguity concerning the meaning of a word or expression used by the legislative body in enacting a statute." *X-Acto Crescent Prods. Co., Inc. v. United States*, 27 Cust. Ct. 190, 192 (U.S. 1951); *see also Yates v. United States*, 135 S. Ct. 1074, 1085 (2015); *Gutierrez v. Ada*, 528 U.S. 250, 255 (2000); *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995); *Jarecki v. G. D. Searle & Co.*, 367 U.S. 303, 307 (1961) ("The maxim *noscitur a sociis*, that a word is known by the company it keeps, while not an inescapable rule, is often wisely applied where a word is capable of many meanings in order to avoid the giving of unintended breadth to the Acts of Congress."); *Brown v. Chicago & N. W. R. Co.*, 77 N.W. 748, 752 (Wis. 1899).

For example, a statute saying "signed, or otherwise adopted or approved," was interpreted "by ordinary principles of noscitur a sociis" as meaning "an approval comparable to a signature." *United States v. Begaye*, 236 F.R.D. 448, 451 (D. Ariz. 2006) (discussing *Campbell v. United States*, 296 F.2d 527, 532-33 (1st Cir. 1961)). In *Jarecki*, this Court applied the maxim noscitur a sociis and said that in a statute having three words in conjunction—"exploration, discovery, or prospecting"—the word "discovery" "gathers meaning from the words around it," and because these words describe activity in the oil and gas and mining industries, "discovery" cannot be applied to development and manufacture of drugs and cameras. 367 U.S. at 307.

In accordance with the noscitur a sociis canon, the term "on sale" should be interpreted by association with both its closest neighbors ("in public use" and "otherwise available to the public") and its more distant neighbors ("patented" and "described in a printed publication"), all of which denote public availability.[19]

2. The "Last Antecedent" Canon Is Inapplicable.

The "last antecedent" doctrine, referenced in the concurring opinion in the Federal Circuit's order denying en banc review, *Helsinn Healthcare S.A. v. Teva Pharmaceuticals USA, Inc.*, No. 2016-1284, 2016-1787, slip op. at 7 (Fed. Cir. Jan. 16, 2018) ("Slip op."), is inapplicable here. The last antecedent rule "provides that 'a limiting clause or phrase . . . should ordinarily be read as modifying only the noun or phrase that it immediately follows'" and

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19. Another related canon, the ejusdem generis rule (according to which, in a series of words of description, a general word can be limited to a meaning similar to that of objects of a like kind with the specified terms), further supports commonality of interpretation here. The U.S. Courts of Customs and Patent Appeals applied the ejusdem generis canon to hold that the term "otherwise manufactured" in a provision stating that "[p]earl, mother of, and shells, not sawed, cut, flaked, polished, or otherwise manufactured" was to "take color and meaning from the enumerated operations, which are to be regarded as manufacturing operations within the purview" of this paragraph. *August Bentkamp v. United States*, 40 C.C.P.A. 70, 73, 77 (C.C.P.A. 1952). "To hold differently would be to ignore the plain meaning of the . . . statutory language and *would in effect eliminate and render meaningless the word "otherwise"* in each of the[] paragraphs [at issue]. This is a result which we believe Congress clearly could not have intended." *Id.* at 77 (emphasis added).

"reflects the basic intuition that when a modifier appears at the end of a list, it is easier to apply that modifier only to the item directly before it." *Lockhart v. United States*, 136 S. Ct. 958, 962-63 (2016) (quoting *Barnhart v. Thomas*, 540 U.S. 20, 46 (2003)).

The concurring opinion suggests that "the doctrine implies that 'to the public' limits only 'otherwise available.'" Slip op. at 7. Here, however, "otherwise" modifies "available to the public," not the other way around. Moreover, the "noun or phrase" immediately before "or otherwise available to the public" is "on sale." If anything, application of the "last antecedent rule" would result in "otherwise available to the public" applying to "on sale."

The structure of § 102(a) does not invite application of the "last antecedent rule," because the type of "limiting clause or phrase" that calls for application of this doctrine is not present in the statute. Application of that canon also results in a cramped reading that is true neither to the provision's actual language nor to its legislative history. *Davis* v. *Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989) ("It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme").

The "last antecedent rule" is not a good linguistic fit, and does not apply here.

G. Confidentiality Obligations Create a Special Circumstance That This Court Has Long Recognized.

Since the days of *Pennock*[20] and *Egbert*,[21] the Court has recognized that confidentiality obligations to an inventor create a special circumstance.[22] In *Pennock*, the Court recognized public accessibility as a key consideration: "[I]f a man dedicates a way, or other easement to the public, it is supposed to carry with it a permanent right of user." *Pennock*, 27 U.S. at 16. The Court was concerned that there "would be no quid pro quo—no price for the exclusive right or monopoly conferred upon the inventor *if the public were already in possession and common use of an invention*." *See id.* at 23 (emphasis added).

In *Egbert*, the Court stated: "[i]f an inventor, having made his device, gives or sells it to another, to be used by the donee or vendee, *without limitation or restriction, or injunction of secrecy*, and it is so used, such use is pubic, even though the use and knowledge of the use may be confined to one person." *Egbert*, 104 U.S. at 336 (emphasis added). The *Egbert* Court similarly considered a sale of an invention for unrestricted public use—"if [an] inventor *sells* a machine of which his invention forms a part, and *allows it to be used without restriction* of any kind, the use is a public one." *Egbert*, 104 U.S. at 336 (emphasis

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20. *Pennock v. Dialogue*, 27 U.S. 1 (1829).

21. *Egbert v. Lippmann*, 104 U.S. 333 (1881).

22. Teva erroneously argues in its opposition brief that Helsinn's "reading of the AIA would require overruling the *Pennock* line of cases." Opp. Br. at 31.

added) (citing *Elizabeth v. Pavement Co.*, 97 U.S. 126 (1877)). *Egbert* thus at least supports that an imposition of a confidentiality restriction can be an exception to an invalidating sale or use.

More recently, in *Pfaff*,[23] this Court recognized that both the on sale and public use bars of § 102 stem from the same "reluctance to allow an inventor to *remove existing knowledge from public use.*" *See Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1379 (Fed. Cir. 2005) (emphasis added) (quoting *Pfaff*, 525 U.S. at 65). "The patent laws [] seek both to protect the public's right to retain knowledge *already in the public domain* and the inventor's right to control whether and when he may patent his invention." *Pfaff*, 525 U.S. at 65 (emphasis added).

This Court's pre-AIA precedent thus recognized the rationale underlying the on sale and public use bars as resting on the public accessibility to the invention, without confidentiality restrictions.

Teva's own brief acknowledges this Court's recognition of the significance of a "limitation or restriction, or injunction of secrecy." Opp. Br. at 6-7 (quoting *Egbert*, 104 U.S. at 336). In an effort to avoid the clear statutory language of § 102(a)(1), Teva misconstrues *Pennock* and relies on what Teva calls "the leading lower-court case," *Metallizing Engineering Co. v. Kenyon Bearing & Autoparts Co.*, 153 F.2d 516 (2d Cir. 1946)), Opp. Br. at 7, ignoring that that case has been vigorously criticized. *See, e.g.*, D. Karshtedt, *Did Learned Hand Get It Wrong?: The Questionable Patent Forfeiture Rule of Metallizing*

23. *Pfaff v. Wells Elecs.*, 525 U.S. 55 (1998).

Engineering, 57 Vill. L. Rev. 261 (2012). Teva's reliance on its characterization of previous case law is inconsistent with the plain language of the statute, its legislative history, the USPTO's interpretation, canons of statutory construction, and this Court's precedent.

The new AIA § 102(a)(1) "on sale" bar explicit requirement that the sale must make the "claimed invention" "available to the public" thus comports with this Court's long-standing recognition of this exceptional circumstance.

Confidentiality has always mattered, and still does. Now, the AIA has expressly and unambiguously incorporated a requirement that "on sale" prior art must make the "claimed invention" "available to the public" in order to fall within the scope of invalidating prior art under § 102(a)(1).

IV. Conclusion

For the foregoing reasons, the judgment of the U.S. Court of Appeals for the Federal Circuit should be reversed.

Respectfully submitted,

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August 30, 2018